THE INTERNATIONAL CENTRE FOR THE SETTLEMENT OF INVESTMENT DISPUTES

In the Matter of Arbitration Between: APOTEX HOLDINGS INC. and APOTEX INC., Claimants, and THE UNITED STATES OF AMERICA, Respondent.	Case No. ARB(AF)12/1 (Revised) Volume 1

HEARING ON JURISDICTION AND THE MERITS

Monday, November 18, 2013

The World Bank
1225 Connecticut Avenue, N.W.
C Building
Conference Room C8-150
Washington, D.C. 20433

The hearing in the above-entitled matter came on, pursuant to notice, at 8:55 a.m. before:

MR. V.V. VEEDER, QC, President

MR. J. WILLIAM ROWLEY, QC, Arbitrator

MR. JOHN R. CROOK, Arbitrator

Also Present:

MR. MONTY TAYLOR
Secretary to the Tribunal

MS. MARTINA POLASEK
Alternate Secretary of the Tribunal

Court Reporter:

MS. DAWN K. LARSON
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Claimant's Representative:

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MS. ROBERTA LOOMAR
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APPEARANCES: (Continued)

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C O N T E N T S

P R O C E E D I N G S

PRESIDENT VEEDER: Well, good morning, ladies and gentlemen. We'll start the first day of this hearing, the 18th of November, 2013, in ICSID Case Number ARB(AF)/12/1.

The Tribunal has received a revised List of Participants attending this hearing, and many of us, I hope, are familiar with each other so we won't go through all the names.

On my left, Mr. Crook; and on my right, you know my co-arbitrator, Mr. Rowley.

I suggest we don't go through all the list of names, but at the end of the day, if you could simply countersign to show that you've attended the day's hearing as we go through the week, that would be more helpful than going through a list every day.

We've received the Parties' joint proposed hearing timetable. We've also received a list of the Witnesses to be orally examined this week. That is all satisfactory to the Tribunal.

There are some outstanding procedural applications of some importance. What we propose you

08:57:15 do is not to deal with them now but to allow them to form part of your respective introductory Opening Statements.

So if that's agreeable to you, we'll proceed now immediately to the Claimants' Opening Statement, not to last more than 45 minutes. We'll then have a short break, and then we'll give the floor for the Opening Statement to the Respondent. And then we'll have another break, and we will then resume as planned with the Claimants' Case-in-Chief.

We plan to finish today for lunch at 12:30 and resume at 2:00, and then at 2:00 to continue, again with a midafternoon break, until 6:00 p.m.

Is that satisfactory so far to both sides? We ask the Claimants first.

MR. LEGUM: It is satisfactory, Mr. President. It may be useful at some point for us to make sure that our list of outstanding issues coincides with that of the Tribunal, but, yes, that is satisfactory.

PRESIDENT VEEDER: A good suggestion. Well

08:58:13 taken.

The Respondent.

MS. McLEOD: It is satisfactory to us, also, Mr. President.

PRESIDENT VEEDER: Thank you very much. So we give the floor to the Claimants for its Opening Statement.

OPENING STATEMENT BY COUNSEL FOR CLAIMANTS

MR. LEGUM: Mr. President, Members of the Tribunal, it is my honor to appear before you today and deliver the Opening Statement of Claimants, Apotex Inc. and Apotex Holdings.

Early August 2009, the Commissioner of the FDA appointed by the Obama administration gives her first policy speech. Commissioner Hamburg announces a new emphasis on effective enforcement. The Commissioner proposes to "send a strong message" by setting a precedent of major sanctions against at least one alleged offender and widely publicizing the action.

Late August 2009, a high-ranking officer in FDA CDER's Office of Compliance announces to a

08:59:27 pharmaceutical industry gathering that "Next week you will be reading about how FDA has placed a company on Import Alert only seven business days after the conclusion of a foreign inspection."

That same officer gave another speech a few months later. He highlighted the exceptional nature of the Import Alert imposed on Apotex. "That Import Alert was implemented 10 days after the completion of an inspection. We've never done that before. Generally, we place companies on an Import Alert after a Warning Letter. This inspection was completed on a Friday. On Monday, FDA Office of Compliance International Alert branch was on the phone with the Executive Officer and asked them what they intended to do."

Mr. President, Members of the Tribunal, we are here today because, as FDA recognized at the time, its actions against Apotex truly were exceptional. FDA had never before rushed to take action against a major pharmaceutical company without any imminent health hazard and without providing any real opportunity for the company to address FDA's concerns.

09:00:53 It has not done it before. It has not done it since. The Apotex case remains without equal.

The Import Alert cut off the supplies Apotex-U.S. depended on for 80 percent of its business.

For the two-year period the Import Alert was in effect alone, Apotex-U.S. and Apotex lost over $500 million in profits. Apotex-U.S. dropped from a market leader in the fifth or sixth position in the U.S. market for generic drugs to the bottom ranks of the top 25. The impact on Apotex of the Import Alert was devastating.

As FDA anticipated, when considering the Import Alert, other generic companies--principally Teva--benefited from FDA taking Apotex off the market. But Teva turned out to have manufacturing deficiencies so serious that FDA initiated a recall of its drugs and patients were hospitalized after taking them, something that never happened with Apotex's products.

One might expect FDA to extend the same severe treatment to Teva and other comparators that it gave to Apotex; not at all is what this record shows.

09:02:26 FDA gave Teva weeks to prepare its proposed Corrective Actions, inspected Teva into compliance by telling it exactly what to do to meet FDA concerns, and reinspected and closed out the Teva Warning Letter within months after it was issued.

The record shows that again and again FDA accorded more favorable treatment to Apotex's competitors than it did to Apotex despite circumstances that were either like those of Apotex or much more serious.

The record also shows a complete lack of due process as concerns Apotex. The Import Alert was adopted with no notice, no reasons made known to Apotex, no opportunity to dispute the charges against it, and no opportunity to present evidence in support of Apotex's own position.

Import Alerts for drug cGMPs are an FDA practice without express statutory or regulatory authorization. The practice is based on an early 20th century law that contemplated inspection of goods at the border. As applied in Apotex's case, the practice accorded Apotex no notice, no access to an impartial

09:03:50 decision maker, no statement of reasons for the Import Alert, no opportunity to contest the evidence in support of the Import Alert, no opportunity to present evidence in support of Apotex's position, and no access to a court for review.

The record, in short, demonstrates a breach of NAFTA's requirements of National Treatment, Most-Favored-Nation Treatment, and the Minimum Standard of Treatment.

The United States deploys a number of strategies to distract from what this record clearly shows. First, it suggests that this case is about the correctness of FDA's cGMP determinations concerning Apotex's facilities, and it relies on a supposed concession by Apotex that its facilities violated GMP requirements. Neither of these suggestions is correct. Apotex's National Treatment and MFN claims address differences in treatment of investments that depend for supply on facilities FDA found to be cGMP noncompliant.

The fact that makes the circumstances like is the FDA finding of noncompliance. Whether FDA was

09:05:24 right or whether FDA was wrong in making any of the findings is not an element of the National Treatment or MFN claim here.

Similarly, the Minimum Standard of Treatment claim here addresses the lack of basic procedural due process afforded Apotex. Whether FDA was right or wrong about Apotex's cGMP compliance, again, is not a part of the claims presented in this case.

Now, Apotex has made it clear from the beginning of this arbitration that it does not agree with the FDA's determination that the facilities at issue violated cGMP. However, Apotex recognized that its manufacturing processes, like those of every company, could be improved. Apotex continually enhances its processes, and it did so extensively at a Etobicoke and Signet. Its position throughout has been that those facilities complied with cGMP. It maintains that position, but it is a position that does not enter into the analysis of the claims here.

Second, the U.S. attempts to discredit Apotex by exaggerating the nature of the cGMP findings FDA made and implying that Apotex's products posed an

09:07:00 imminent public health risk. At one point it even goes so far as to discuss Apotex in the same breath as a compounding facility in New England that killed and injured scores of patients. Apotex categorically rejects this tactic.

Let me be clear; there is no evidence that any Apotex product ever injured a patient in the United States, unlike comparators such as Teva, whose products resulted in the hospitalization of dozens of patients. In fact, FDA recognized at the time of the Import Alert, through both words and deeds that we will review alert on this morning, that there was no serious risk to patients.

Third, the U.S. places great reliance on Legal Arguments that attack not the case that Apotex presented, but an invented variation of it.

In reading the Rejoinder, time and time again I find myself asking, "Did we make that argument? I don't remember making that argument." The answer is we didn't. The U.S. repeatedly builds straw men and knocks them down.

Fourth, when the U.S. does grapple with the

09:08:22 record, as it does in the portion of its Rejoinder addressing the new materials on comparators, it tends to do so in the form of terse bulleted statements in text, bristling with dense footnotes that are difficult to read but give the impression of support for the text. They do not. The sparse evidence submitted by the U.S. does not withstand scrutiny.

In our presentations in the coming sessions, we will spend a great deal of time reviewing the evidence in this case. As is to be expected in a case with substantial National Treatment and Most-Favored-Nation Treatment Claims, much of this case addresses the treatment and circumstances surrounding the comparators. The comparators are not Parties to this case. They are not Witnesses in this case. The evidence concerning them is documentary.

Our goal is for the Tribunal to come away from our presentations with a clear understanding of the state of the record concerning the comparators as well as Apotex.

Now, as the Tribunal is aware, the United States elected not to test the credibility of any of

09:09:41 Apotex's Fact Witnesses by calling them to testify at the hearing. Apotex's Witness Statements are in the record, and their credibility is unchallenged. The Tribunal will not hear this week from Jeremy Desai, Gordon Fahner, Bernice Tao, Kiran Krishnan, Bruce Clark, Ed Carey, Jeff Watson, or John Flinn. That fact can in no way diminish the importance of the Witness Statements they have submitted.

The presentations we will give this week will be detailed, but time will not permit us to repeat all of the points made in Apotex's written submissions. Apotex maintains all of those positions. The fact that we do not address one here does not signify that we have abandoned it.

Our main presentation will begin with a review of the facts by Mr. Hay. We will then turn to jurisdiction. We will show that the objections to jurisdiction made by the United States are without merit and should be dismissed. We will begin our presentation on the Merits likely towards the end of the day today or possibly tomorrow. We will demonstrate that the U.S. breached its obligations of

09:11:05 National Treatment and MFN Treatment by according Apotex and its investment's treatment less favorable than that accorded to U.S. and, third-country-owned investors and investments in like circumstances.

Our plan is to begin tomorrow, morning session, by first presenting Sheldon Bradshaw and then Ron Johnson for cross-examination by the United States. We will then continue our presentation on National Treatment and MFN Treatment, likely bringing it to a close on Tuesday afternoon or possibly Wednesday morning. We will conclude our Case-in-Chief on Wednesday by demonstrating that the United States breached the Minimum Standard of Treatment under Article 1105(1) by failing to accord Apotex basic due process in the adoption of the Import Alert.

The Apotex team welcomes the Tribunal's questions at any time, and we thank you in advance for your attention to our presentations.

Now, this takes me to the end of the Opening Statement that I had prepared. And I'm happy to take up the procedural issues now, if you wish.

PRESIDENT VEEDER: Yes.

09:12:23 MR. LEGUM: All right. So according to our list, there are four outstanding issues. One is the motion to exclude evidence submitted by Apotex in its Rejoinder on Jurisdiction. The other is the U.S.'s application to not allow reference to new Legal Authorities. The third is the scheduling for the Closing Statements on Monday or possibly Tuesday of next week. And then the fourth issue is the time for direct examinations of Expert Witnesses.

Now, on the fourth point, I believe that we have reached an agreement with counsel for the United States on the time for direct examination of Experts. The Agreement is 30 minutes maximum total for each side. So Apotex has two Experts that will be called. Our direct examination of those two Experts combined will not exceed 30 minutes. U.S. has only one Expert, so it is not as complicated a mathematical equation.

On the scheduling for Closing Statements--

PRESIDENT VEEDER: Is that confirmed, that Agreement between the Parties? If so, we can put it to bed now.

MS. McLEOD: Yes, Mr. President.

09:13:51 PRESIDENT VEEDER: Okay. So it will be 30 minutes in total for the Parties' respective Expert Witnesses for direct examination. I need not add, but I will, that that will not necessarily affect the Tribunal. We may have questions that we may wish to put. I take it that doesn't cause any difficulty for either side.

MR. LEGUM: Of course not.

PRESIDENT VEEDER: Well, let's put that aside. That's agreed.

So we only have three.

MR. LEGUM: Good. So three are left. Taking them in--somewhat in reverse order, the scheduling of the Closing Arguments. The Parties have attempted to reach an agreement on that. We have not been able to. I think on that issue we would simply like the Tribunal to make a decision on it. I'm happy to present arguments on it, if you wish. I think the arguments are set out in the written submissions. I'm happy to leave it there, but I'm also happy to take it up if you wish.

PRESIDENT VEEDER: Leave it there for the

09:14:51 moment.

MR. LEGUM: Okay.

So that leaves two contested issues: The motion for exclusion of new evidence, and the new Legal Authorities. So I'll begin with the motion for exclusion of new evidence.

The procedure that the Parties designed in this case and that the Tribunal approved was one where the U.S.'s response to Apotex's Memorial would be stated in its Counter-Memorial. And based on that proposition, we scheduled the disclosure portion of this case after the U.S. Counter-Memorial. There is an explicit provision in the Procedural Order that makes clear that new evidence can be submitted with the second pleadings of a Party only if it addresses matters raised in the preceding pleading, and in addition, the Parties agreed to a very compressed timetable between the U.S. Rejoinder and this hearing.

Now, the Parties disagree about whether the new materials that have been offered by the United States address matters raised in the Memorial or in the Counter-Memorial. Apotex's submission is that

09:16:21 they clearly address matters that were fairly and fully presented in the Memorial. We encourage the Tribunal to read the portions of Apotex's Reply that the United States relies on to support the idea that these were new matters raised for the first time in the Reply. We are confident that the Tribunal, if it engages in that exercise, will reach the same conclusion that we did, which is that these are all matters that were raised in the Memorial and should have been addressed in the Counter-Memorial. And, in fact, the United States has not presented any clear explanation as to why it is that it could not address or present those materials with its Counter-Memorial.

Apotex had--as a result of the United States waiting until its Rejoinder to raise these issues, Apotex had a little over two weeks to digest these new materials and to prepare a response. It had no opportunity to test these new materials by requesting documents concerning them from the United States, and this put us in a very difficult position. We felt that we were sandbagged by this tactic, and while we were able to prepare a response, because of the very

compressed Schedule, we have not the confidence that we would have had with our response had we been granted the time that was contemplated by the schedule to address these matters in our Reply.

We, therefore, feel that the submission of these new materials is inconsistent with the procedural rules that were agreed for these proceedings, and would urge the Tribunal to exclude them from the record.

I'll make one final point on that issue, which is that Apotex submitted no new evidence with its Reply on the comparators--most of these comparators in question, the comparators that are the subject of our application. So unless the Tribunal has any questions on that topic, I will turn to the Second Procedural Order.

PRESIDENT VEEDER: Just before you do--

MR. LEGUM: Yes, please.

PRESIDENT VEEDER: As I recall, your application goes beyond striking evidence but also striking pleading submission. Is that maintained?

MR. LEGUM: Well, the portion of the pleading

that recites and relies on the evidence, yes.

PRESIDENT VEEDER: Okay. Fine. Thank you.

Please continue.

MR. LEGUM: Yes.

So turning now to the question of the--whether Apotex can refer to new Legal Authorities during the course of this hearing.

In its Rejoinder, the United States put forward two new Legal Arguments concerning Article 1105 that had not previously been advanced in these proceedings.

Now, the procedure that the Parties agreed to, as I've just explained, limits when new evidence may be submitted in the proceedings. It does not contain any provisions that address when Legal Arguments on the Merits may be advanced or Legal Authorities supporting arguments on the Merits may be advanced. For this reason, Apotex did not object to the U.S. raising these two new arguments in its Rejoinder for the first time. Apotex does, however, believe that it should have the right to respond to these legal arguments that were raised for the first

in the Rejoinder.

Our experience at other hearings has been that there is no restriction on a Party's ability to refer to Legal Authorities during the hearing, but advance notice is provided of that to the other Party, which is what we did by transmitting the specific Authorities that we intended to refer to to the United States on Thursday.

Now, we did read the U.S. letter of Friday and felt that it did make one fair point, which is that these Legal Authorities are somewhat lengthy, and that it was difficult for--it was difficult for the United States to identify the specific portions of those Authorities that we were going to put into issue.

We have, in response to that, given the United States a detailed statement of the specific paragraphs and pages of each Authority and which point each Authority goes to as well as the actual quotations from each Authority that we would refer to. So the U.S. has that from this morning.

PRESIDENT VEEDER: Has that been copied to

the Tribunal?

MR. LEGUM: I would be happy to provide a copy to the Tribunal.

PRESIDENT VEEDER: Would there be any objection to the Tribunal seeing that?

MR. SHARPE: Mr. President, we would respectfully request that the Tribunal rule on the issue, first, of whether the new Authority should be admitted into the record before it effectively accepts new briefing on these points.

PRESIDENT VEEDER: We'll develop that later. We'll come back.

So obviously that's an issue we have to address.

Continue, Mr. Legum.

MR. LEGUM: As I mentioned, the arguments that these go to concern Article 1105. As the Tribunal will recall from the Opening Statement I just gave, 1105 will come up on Wednesday of this week and not before.

There's two other points I would like to make. First, it defies logic that one Party can raise

09:22:53 a new legal argument in its last submission and the other Party not to be permitted to respond to it. In our submission, it would be helpful for the Tribunal, in reaching a decision that is informed on the issues before it, to know, for example, that there are three Tribunals that have grappled with a similar issue and have ruled in a specific way, and so our submission is we should be permitted to refer to these Legal Authorities.

I guess the last point that I would note is that there are two Legal Authorities--I believe that the last two in the list--that don't address a new argument, that simply address an argument that was advanced, I think, in an earlier submission, and we have no difficulty with dropping those.

PRESIDENT VEEDER: Can you tell us which cases those are that you're dropping?

MR. LEGUM: It's CLA-637, CLA-638.

I can provide you the specific case reference if you'd prefer, or we can leave it at that.

PRESIDENT VEEDER: That's fine. Thanks.

MR. LEGUM: So that is all that I would say

09:24:29 at this point on these issues. Happy to respond to any questions the Tribunal might have.

ARBITRATOR CROOK: Thank you, Counsel. Could you remind us the new 1105 arguments to which this responds?

MR. LEGUM: Yes.

So the first is the U.S.'s argument that Article 1105 of the NAFTA applies only to a denial of fair and equitable treatment to an investment. It does not apply to a denial of fair and equitable treatment to an investor with respect to an investment. So that's one.

And then the other is the U.S. asserts that there is no jurisdiction in the world that affords due process before an Import Alert is adopted. So that's the other one.

Thank you.

PRESIDENT VEEDER: Well, you've taken a very efficient 25 minutes.

Would you like a 5-minute break now, or are you happy to continue?

MS. McLEOD: Yes, Mr. President. We'd

09:25:54 appreciate 5 minutes, and then we'll be ready to go.

PRESIDENT VEEDER: Let's take a 5-minute break.

(Brief recess.)

PRESIDENT VEEDER: Let's resume. Ms. McLeod.

OPENING STATEMENT BY COUNSEL FOR RESPONDENT

MS. McLEOD: Mr. President, Members of the Tribunal, I am Mary McLeod, the Acting Legal Adviser of the U.S. Department of State. It's a privilege for me to open these proceedings for the United States. I will provide a short introduction to the U.S. arguments that are at heart of our defense of this case. We look forward to presenting these arguments in greater detail in the coming days.

For the Tribunal's convenience, we have distributed an agenda for the presentation of the U.S. arguments and Witnesses this week. We have also distributed binders with today's PowerPoints. I regret that I cannot stay for all of the proceedings because I am required to attend the Assembly of States Parties of the International Criminal Court later this week. I do plan to return next week for the Parties'

09:37:25 Closing Arguments.

As the Department's senior lawyer, I'm appearing today not simply to highlight the key legal arguments for the United States. I also want to stress the importance of this case to the U.S. Government. This case is not only by far the largest dollar-value investment claim that the United States has ever faced, but also is perhaps the most troubling NAFTA Chapter 11 case brought against the United States. Apotex's arguments, if accepted, would undermine the Government's ability to prevent the importation into the United States of adulterated drugs. It is inconceivable that the NAFTA Parties intended, by concluding the Treaty, to relinquish this fundamental authority to protect public health and safety.

But before addressing Merits issues, I want to say a few words about Claimants' jurisdictional claims. We are deeply concerned that Claimants here seek to expand the boundaries of NAFTA Chapter 11 far beyond anything the NAFTA Parties contemplated when they concluded the Treaty.

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09:38:29 You all have sat in previous investment arbitrations against the United States, and I don't need to remind you of the United States' strong commitment to investor-State arbitration as an appropriate mechanism for resolving disputes between foreign investors and host governments. The United States has included investor-State arbitration provisions in scores of bilateral and multilateral investment agreements, including NAFTA Chapter 11. But the United States and its NAFTA partners expressly limited their consent to investment arbitration to disputes brought by qualifying investors with covered investments. The NAFTA Parties did not consent to adjudicate trade-related claims or to pay trade-related damages in investment arbitrations.

In our view, Apotex has sought to transform what is really a trade claim into an investment claim. Apotex seeks to recover money damages arising from a trade measure--an Import Alert--addressed to two of its Canadian pharmaceutical facilities. But Chapter 11 arbitration is not the right forum to resolve such disputes. To the contrary, the NAFTA Parties made

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09:39:38 clear that trade disputes are to be resolved through consultations or State-to-State arbitration under NAFTA Chapter 20.

Apotex Inc. is not an investor with investments in the United States. To the contrary, Apotex Inc. is a Canadian exporter of generic drugs. Apotex Inc. does not claim to manufacture its drugs in the United States. Nor does it claim to prepare its drug applications in the United States. All of those activities occur in Canada. Apotex Inc. admits that it has no testing or manufacturing facilities, no employees, and no sales offices in the United States.

Apotex has even represented in U.S. court that--and you will see this on the slide--"Apotex Inc. does not directly sell any products of any kind in the U.S.; "Apotex Inc. has put nothing into the stream of commerce" in the United States; and "None of the relevant work" preparing Apotex Inc.'s abbreviated New Drug Applications--or ANDAs--is performed in the United States; rather, "all such work occurs in Canada."

In this arbitration, moreover, Apotex has

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09:40:52 acknowledged it pays no taxes in the United States on transactions involving its putative U.S. investments.

Apotex thus advances the extraordinary claim that a Canadian exporter with no presence of any kind in the United States qualifies as an investor with investments in the United States for purposes of NAFTA's investment chapter.

The only investments Apotex Inc. claims in the United States are its Abbreviated New Drug Applications. Apotex refers to its ANDAs as "marketing authorizations."

But that is not what ANDAs are called under U.S. law. Whether unapproved, tentatively approved, or finally approved, an ANDA remains an Abbreviated New Drug Application. Even after they are approved, FDA has the ability to revoke ANDA approvals for a wide variety of reasons, including violations of current good manufacturing practice, or cGMP.

Apotex asserts that its ANDAs are investments for purposes of Chapter 11 because they are intangible property under Article 1139(g). Apotex also asserts that its ANDAs constitute interests arising from the

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09:42:06 commitment of capital in the United States under Article 1139(h). Apotex's applications are neither property nor investment interests. As the Tribunal in the Apotex I and II claims concluded, for a company like Apotex Inc., whose manufacturing facilities are outside the United States, an ANDA is simply an application for permission to export goods. That is--and you have this on a slide--"Even assuming that the ANDAs were Apotex's exclusive property, they remained no more than applications for permission to (in this case) export, and as such neither fell within NAFTA Article 1139(g), nor constituted 'investments' as contemplated more generally by NAFTA Chapter 11."

A principal reason for this, the Tribunal confirmed, is that U.S. law affords FDA significant discretion to revoke even a finally approved ANDA for any number of stated reasons provided by law. One of these bases for revoking an approved ANDA, relevant to this case, is a violation of current good manufacturing practice. Even finally approved ANDAs, therefore, are revocable, contingent interests; they are not investments.

Because ANDAs are not investments for purposes of NAFTA Chapter 11, the Apotex I and II Tribunal concluded that Apotex Inc. is not an investor in the United States. The Tribunal thus unanimously rejected Apotex's claim for lack of jurisdiction.

The Apotex I-II Tribunal not only dismissed Apotex's claims in their entirety, it also ordered Apotex to pay 100 percent of the United States legal and arbitration costs. The Tribunal did not do so because of Apotex's conduct during the proceedings. Unlike in this case, in those proceedings, Apotex consented to have its jurisdictional claims heard separately from the Merits, and the Tribunal commended Apotex from having presented its case efficiently and professionally.

Instead, the Tribunal ordered Apotex to pay all costs because it found that Apotex's claims were manifestly outside the scope of Chapter 11. The Tribunal stressed--and, again, you have a slide--"The fact remains that Apotex initiated two sets of proceedings against the Respondent, and thereby caused the Respondent to incur costs, in circumstances where

neither proceeding was within the scope of NAFTA Chapter 11, and no claim was properly before this Tribunal.

"The Respondent has raised entirely appropriate objections, and on the basis of the Tribunal's findings, ought never to have been embroiled in this process. In all the circumstances, the Tribunal sees no justification for the Respondent to bear any of the costs it has (reasonably) incurred."

Here, too, we believe that the United States ought never to have been embroiled in this process, and that this Tribunal should recognize and accept the Apotex I-II Tribunal's unanimous decision, which is res judicata in these proceedings.

Apotex argues that the Apotex I-II Award is inapposite, claiming that the issues here are different. That argument, of course, is to be expected, given that the Tribunal unanimously dismissed one of the key jurisdictional claims that Apotex advances here. Apotex notes that it brought its previous two claims based on tentatively approved

ANDAs, rather than on finally approved ANDAs. But Apotex did so not because it lacked finally approved ANDAs at that time. It did so because of its belief that, for purposes of NAFTA Chapter 11--and I refer you to the slide again--"distinctions between tentatively approved ANDAs and finally approved ANDAs are distinctions without a difference." The Apotex I and II Tribunal agreed with Apotex on this point, expressly finding that ANDAs are not investments regardless of whether they were approved or merely pending.

I urge the Tribunal to read the Apotex I and II Award carefully. We are confident that you will agree with that Tribunal's cogent analysis and careful reading.

In addition, I would ask you to reflect on the Tribunal's recognition of the potential implications of Apotex's sweeping jurisdictional claims. The Tribunal stated--and this is on another slide--"As the Respondent has pointed out, if preparing an ANDA could constitute an 'investment' under Article 1139, then any Canadian or Mexican

exporter requiring U.S. regulatory clearance to have its good sold by the Third Parties in the United States could potentially bring an investment claim under NAFTA Chapter Eleven, whenever such clearance, in the exporter's view, was wrongly denied or delayed. This would be so regardless of whether the exporter made or sought to make an investment in the United States. The Tribunal is persuaded by the Respondent's submission that allowing a mere application for regulatory clearance to export goods into the United States to give rise to an investment claim under Chapter 11 would be inconsistent with the core objectives of NAFTA's investment chapter."

The Tribunal's statement is prescient and seems to predict this very case. Here, Apotex essentially argues that the United States failed to provide the necessary clearance to have Apotex's goods sold by Third Parties in the United States. And Apotex now relies on its ANDAs as the jurisdictional hook for Apotex Inc.'s investment claim. That is precisely what concerned the United States in the previous case, and it's what the Apotex I-II Tribunal

correctly sought to prevent with its jurisdictional Award.

The implications of Apotex's argument extend far beyond the United States and its NAFTA partners. Apotex Inc. claims to export drugs to 115 countries around the world, including the United States. Apotex presumably is required to comply with the applicable regulatory requirements of all 115 countries in which its drugs are sold. But this does not make Apotex an investor in all 115 countries, any more than Apotex's submission of its ANDAs transforms it into an investor in the United States. Compliance with local law is required of everyone that seeks to market goods in the United States. It is not a ticket to investment arbitration.

There is another, equally troubling aspect of Apotex's claims, one that concerns Apotex Holdings' U.S. enterprise Apotex Corp. As you can see from the corporate chart on the slide, Apotex Corp. is not owned or controlled by Apotex Inc. Apotex has acknowledged in this arbitration and in U.S. court proceedings that the two companies are separate and

independent. Accordingly, Apotex Corp. cannot be an investment of Apotex Inc. And yet Apotex Corp. claims injuries in the United States based on Measures taken against Apotex Inc. in Canada.

According to Apotex, because Apotex Inc. and Apotex Corp. are in the same corporate family, Apotex Corp. can claim damages for actions taken against its corporate relative. That cannot be correct. If that argument were accepted, a multinational company could routinely transform trade-related Measures affecting one corporate relative into an investment claim affecting other corporate relatives, no matter how distant.

In other words, a company like Apotex could use its corporate relatives as a kind of Trojan horse to obtain jurisdiction for an investment claim. The NAFTA Parties prevented a Claimant from doing this by requiring, in Article 1101, that the Claimant establish a legally significant connection between the challenged Measure and the investor and its investment. Here, Apotex has failed to establish any legally significant connection between the sole

challenged Measure (the Import Alert) and Apotex Corp.

Mr. President, Members of the Tribunal, we believe that both Claimants in this arbitration--Apotex Inc. and Apotex Holdings--impermissibly seek to expand the boundaries of NAFTA Chapter 11 far beyond anything the NAFTA Parties contemplated when they concluded Treaty. Their claims, in our view, are manifestly outside the scope of Chapter 11 and should be dismissed for lack of jurisdiction.

Let me turn on to our second principal concern with Apotex's claims, which relates to the Merits. The Merits arguments are, of course, inextricably linked to the facts of this case, most of which are not disputed. In short, there is no dispute that FDA found major, recurrent violations of U.S. laws and regulations during its inspections of Apotex's Etobicoke and Signet facilities. Apotex accepted responsibility for those violations and pledged corrective action to return to compliance with U.S. law.

Health Canada corroborated FDA's findings and

placed Etobicoke and Signet under close, continuous, on-site supervision for more than a year. Apotex retained several third-party consultants who confirmed FDA's findings. Apotex declined to stop shipping drugs to the United States from Etobicoke and Signet despite its acknowledgment of the serious, systemic problems with its manufacturing practices at those facilities.

FDA then issued a guidance memorandum, called an Import Alert, which notified FDA field personnel of the cGMP violations. That memorandum provides information that field personnel could (but were not required to) use when determining whether to detain and ultimately refuse admission of drugs from Etobicoke and Signet. After FDA field personnel detained Apotex's drugs, they informed Apotex of its right to submit evidence at a detention hearing. Apotex declined to respond or to participate in the hearing.

Now, four years later, Apotex makes two Merits claims. First, it claims that FDA took enforcement action against Apotex, but didn't take

comparable action against other companies in like circumstances. That's the crux of its National Treatment and MFN Treatment Claims under Articles 1102 and 1103.

Second, it claims that FDA failed to provide Apotex with a hearing and other procedural rights before adding Apotex to the Import Alert.

Each of these claims presents very serious implications for the U.S. Government which, if found meritorious, would impact our Government's ability to protect U.S. consumers. Apotex's Article 1102 and 1103 claims are extremely troubling, as they ask the Tribunal to evaluate FDA's exercise of enforcement discretion in matters of public health. Even worse, Apotex seeks to impose on the United States a binary choice. According to Apotex, if FDA finds cGMP violations of regulatory significance with respect to a facility, it must take the same enforcement action it has taken against another company with cGMP violations, regardless of the specific nature of the violations and any factors weighing for or against such action with respect to the particular facility

and drugs concerned. Either it has to bar all products from noncompliant facilities, or it can bar none of them.

Apotex thus seeks to strip FDA of the regulatory discretion that is at the heart of its public health mandate. This rule would require FDA to ignore the many factors that it routinely considers when exercising that discretion. It would radically alter the way that FDA operates today, and the way that the agency has operated for decades. This result would have serious implications not just for FDA, but also for other domestic drug agencies, which similarly must exercise discretion when regulating the importation and sale of pharmaceuticals.

Alternatively, Apotex's Experts would have this Tribunal step into the shoes of FDA and evaluate how those factors were applied to Apotex and other companies. With respect to the Israeli firm, Teva Pharmaceuticals, Messrs. Bradshaw and Johnson invite the Tribunal to consider--and these factors are on a slide--"how Apotex's cGMP violations were more serious than Teva's; how the risk to consumers as a result of

Apotex's cGMP violations was greater than the risk to consumers as a result of Teva's; how Teva's response to the violations was superior to that of Apotex's; and whether any of the products implicated were medically necessary or in short supply."

There are two fundamental problems with this request. First, neither this or any other international tribunal could properly evaluate the relative seriousness of each company's cGMP violations, the potential risk to consumers, the appropriateness of each company's response, and the medical necessity or shortage of drugs manufactured at each facility. The Tribunal simply does not have the technical expertise or the knowledge of the applicable laws, regulations, or agency practice to make these determinations.

Second, the Tribunal does not have the mandate to step into FDA's shoes and second-guess its work. The NAFTA Parties authorized Chapter 11 Tribunals to evaluate Measures adopted or maintained by the NAFTA Parties against the substantive standards set forth in the Treaty. But that does not mean that

the NAFTA Parties intend for investment tribunals to sit retrospectively in judgment of the discretionary exercise of a sovereign power, particularly with respect to the protection of health and well-being of that sovereign's citizens. This is especially true here, where that authority was exercised in accordance with the long-standing domestic law and well-established FDA practice; where agency personnel exercised their regulatory authority in good faith; and where the decisions were made rationally, in light of all available information.

FDA's decision-making involves complex issues of law, science, and public policy. FDA makes many difficult choices, often balancing drug safety against drug availability. These decisions have life-and-death consequences for millions of U.S. consumers. The Tribunal, we submit, should refuse the invitation to play the role of the national drug authority and entertain the comparisons posed by Apotex's legal Experts.

In any event, the evidence demonstrates that Apotex was not accorded less favorable treatment than

09:57:10 the treatment accorded to any investor or investment in like circumstances. The evidence shows that there were sound reasons for FDA to have adopted an Import Alert for two of Apotex's Canadian facilities, as well as other of dozens of other pharmaceutical companies with cGMP violations, while refraining from adopting an Import Alert or taking enforcement action against other companies.

Members of the Tribunal, we consider Apotex's Article 1105 claim to be no less troubling. Under Apotex's proposed rule of Customary International Law, a State would be required to provide notice and an oral hearing before it could advise its field agents to detain adulterated drug products. That is, according to Apotex, international law requires that a State continue allowing importation of drugs lawfully deemed to be adulterated while the Parties litigate over the State's import decision. The implications of any such rule would be enormous and would endanger public health and safety.

It is not surprising that Apotex has failed to identify a single State that provides the

09:58:21 procedural rights that Apotex claims in this arbitration are required, let alone establish the Customary International Law requires them. Apotex's pleadings discuss relevant practice from Australia, Canada, the Netherlands and New Zealand, but Apotex does not argue that any of these States provide such procedural rights before denying importation of adulterated drugs.

To the contrary, the evidence suggests that States can and do take decisive action to protect public health when necessary. Apotex itself submitted evidence of how Australia's drug authorities responded to problems found at Apotex's Etobicoke and Signet facilities. This is, again, on a slide. Australia imposed "nonnegotiable" demands on Apotex. Apotex-Australia reported to Apotex Inc.: "We are to suspend all shipments of products manufactured at the Signet and Etobicoke sites for Australia with immediate effect."

Apotex does not claim that Australia provided Apotex with a hearing or the other procedural rights before imposing these nonnegotiable demands. Instead,

09:59:34 Australia decisively shut its border to Apotex's drugs and then presumably offered whatever procedural rights are required under Australian law.

The United States similarly provided Apotex with abundant procedural rights before and after adding Apotex's facilities to the Import Alert. But Apotex chose not to avail itself of any of these rights. Apotex never protested or challenged FDA's cGMP determinations and does not do so in this arbitration.

Apotex never contemporaneously protested or challenge the addition of Etobicoke or Signet to the Import Alert through several mechanisms provided under U.S. law. Apotex never availed itself of an administrative hearing to challenge the detention of its drugs, a hearing for which it received notice in the detention documents themselves. And Apotex never brought judicial proceedings to challenge FDA's actions.

In short, Apotex failed to assert any of the administrative or judicial remedies available to it, opting instead to acknowledge its violations and take

10:00:40 steps to bring its manufacturing facilities into compliance with U.S. law. And yet, in this arbitration, Apotex seeks to shift the burden to the United States to demonstrate that these remedies would have been effective, if Apotex actually had invoked any of them.

It is clear why Apotex did not invoke its rights to challenge FDA's actions administratively or in court. Apotex had admitted that Etobicoke and Signet were not cGMP-compliant. Apotex had admitted that those violations were "significant." Apotex's CEO had admitted that its "quality systems lack quality." Apotex's own third-party consultants had confirmed FDA's findings. Apotex required over a year to feel comfortable enough with its cGMP fixes to invite FDA back for a reinspection. Even then, FDA found dozens of cGMP violations during its reinspection, many of them repeat violations from 2008 and 2009.

Members of the Tribunal, these are the reasons why Apotex failed to challenge FDA's actions through the available mechanisms under U.S. law. And

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10:01:51 these are the reasons that its claims in this arbitration are baseless. Apotex is using this arbitration to ask the American taxpayer to reimburse Apotex for the costs of bringing its Canadian manufacturing facilities up to the minimum regulatory standards required for exporting its products to the United States for sale by others. The Tribunal should reject Apotex's improper request.

Mr. President, Members of the Tribunal, I hope my remarks this morning give you a better sense of why the United States is so troubled by Apotex's claims. We respectfully request that you dismiss the claims in their entirety and award full costs to the United States.

Before concluding, I would note that we are pleased to make available for examination the four U.S. Fact Witnesses: Debra Emerson, Lloyd Payne, Michael Goga, and Carmelo Rosa.

Ms. Emerson was a lead investigator for the December 2008 Etobicoke inspection. Her inspection revealed major cGMP violations, and recommended that had FDA take appropriate enforcement action.

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10:02:55 Mr. Payne was lead investigator for the August 2009 Signet inspection. His inspection likewise revealed major cGMP violations. He, too, recommended that FDA take appropriate enforcement action.

Mr. Goga was the lead investigator for the January and February 2011 reinspections of Etobicoke and Signet. His inspection likewise revealed significant cGMP violations. He recommended that the FDA maintain enforcement action against both facilities.

Apotex stated in its Reply that the cGMP determinations are legally irrelevant to these proceedings. It thus is surprising that Apotex has decided to call three witnesses who will testify only about the cGMP findings. In any event, we're pleased to present them here at hearing.

The Fourth Fact Witness is Carmelo Rosa. The Dr. Rosa is a Division Director in FDA's Center for Drug Evaluation and Research, or CDER. CDER is the entity that determined that Etobicoke and Signet were not compliant with cGMP. CDER recommended that the

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10:03:58 two facilities be added to the Import Alert in August of 2009 and again recommended that the facilities be removed from the Import Alert in 2011. Dr. Rose thus is well placed to testify about those matters.

Finally, we will present our legal Expert, William Vodra. Mr. Vodra was the principal drafter of the cGMP regulations when he worked at the FDA in the 1970s. During his 30 years of private practice, including as head of Arnold & Porter's FDA law unit, he specialized in advising numerous pharmaceutical companies on FDA regulations, particularly cGMP. There is no one better placed to answer any questions you may have about the applicable legal regimes.

Mr. President, Members of the Tribunal, that concludes the Respondent's Opening Statement. On behalf of the United States, I thank you for your attention. And I am now going to call upon my colleagues, Lisa Grosh, and Jeremy Sharpe to address the procedural issues, if that's satisfactory.

PRESIDENT VEEDER: Thank you very much for coming here. And thank you very much for the submissions.

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10:04:59 Before we move on, we've got a slight technical problem. We'd just like to pause because our screens are not working.

Can we just see what we can do about that?

(Pause.)

PRESIDENT VEEDER: Let's continue.

MS. GROSH: Good morning, Mr. President. I would like to address some of the procedural issues that were raised by the Claimant and that the Tribunal is considering. And at some points I may refer to my colleague, Mr. Sharpe, who can add some additional points.

I would like to start my remarks by just noting that all of these procedural issues really do go to the fundamental fairness of these proceedings, and to the entitlement of the Parties to be treated with equality in all matters of being heard.

Let me begin first with the Closing. The United States provide, as did the Claimant, proposals for addressing timing of the Closings. We were fortunately able to agree on the length of those closings, but it is the timing that is of concern.

10:07:43 Now, Apotex has put forward--and the Tribunal has both of these submissions. Apotex has put forward a proposal that would give the Respondent just over a lengthened coffee break to provide its Closing, and we note that the Claimant will have had over the weekend to prepare both answers to the Tribunal's questions and what essentially is its Closing, after having heard the Respondent's presentation.

We would submit, Mr. President and Members of the Tribunal, that providing the United States just over a lengthened coffee break to provide its Closing in response to the Claimants' Closing would be grossly insufficient and would not be fair to the United States.

Now, we have put forward two alternatives. We believe that the first alternative would be the fairest and would give the United States the--essentially the same opportunity as the Claimant in providing what essentially would be the same amount of time to address the Tribunal's questions, but then overnight to prepare a Closing that could address the Claimants' aspect of the Closing that would address

10:08:50 the United States presentation. And we would just note that the Claimant would have the full weekend to prepare both.

We have, nonetheless, provided an alternative because we recognize that the Tribunal may, in fact, wish to close these proceedings at the end of Monday, and we believe that our proposal--our alternative proposal for concluding the hearings on Monday would amply give and would really be the minimum amount of time that would be fair in allowing the United States the opportunity to prepare its Closing, which would afford it the ability to address both the Tribunal's questions and Claimants' Closing remarks.

I would now like to turn to the Claimants' request to strike the evidence and arguments that were provided in the United States' Rejoinder on the Merits. And, again, I would just note that what the United States is asking for is nothing more than fairness. Apotex seems to bristle at the role of the Respondent in being able to have the last word and respond to the arguments put forward by the Claimant.

I would note again that the Claimant, and the

10:10:03 role of the Claimant has the burden to demonstrate that its claims fall within the jurisdiction of this Tribunal based on the provisions of the NAFTA, and also that its claims meet the substantive standards of the NAFTA.

And so what the United States has done through its two pleadings--the Counter-Memorial and the Rejoinder on the Merits--is simply been to respond specifically to the arguments put forward by the Claimant or its reasons for which it cannot meet its burden or why the burden should shift to the United States.

What we view as the Claimants' attempt in this regard is simply to restrain the United States' ability to properly put forward its defense and respond to the arguments that Apotex has put forward.

I would note here our two letters that we submitted to the Tribunal on October 31 and November 6 in responding to the Claimants' request to strike that we provided specific details as to the arguments that we were responding to. Specifically, the argument that Claimant offered which was that lesser

10:11:21 comparators should be considered by the Tribunal; and, secondly, that the burden to develop comparators should be shifted to the United States.

Let me just see if my colleague, Mr. Sharpe, has anything further to add on that point.

MR. SHARPE: Thank you, Mr. President, Members of the Tribunal.

If I could just make a few comments about Claimants' representations today. Apotex argues that the U.S. Rejoinder made two new legal arguments, first, Article 1105(1) applies only to investments and not investors; and, two, that Apotex has pointed to no State practice showing that States require oral hearings and--provide oral hearings and other procedural rights before refusing admission of adulterated drugs.

Let me just make three points on these arguments.

First, Article 1105(1), United States clearly addressed this in our Memorial--in our Counter-Memorial, and I would just point to Apotex's own Reply, which states at Paragraph 389, "Contrary to

10:12:33 the U.S. assertion, Apotex has amply demonstrated that the U.S. denied Apotex's investments, the Minimum Standard of Treatment compelled by NAFTA Article 1105. Apotex clearly understood the U.S. argument in our Counter-Memorial as reflected in its represent representations of our argument in its own Reply."

The second--well, I would just note before I go on, the United States' argument in this regard as it's called is simply to point the Tribunal to the text of Article 11--

PRESIDENT VEEDER: Excuse me for interrupting. I didn't quite catch the paragraph number. It didn't come up on the transcript.

MR. SHARPE: The paragraph is 389. Yes, 389.

PRESIDENT VEEDER: Thank you.

MR. SHARPE: The second point is that the United States is simply pointing the Tribunal to Article 1105(1) itself. We think it would be unfair and even impermissible to deny any Party the opportunity to refer the Tribunal to the text of a treaty in an investment Treaty arbitration.

Point Number 2. Apotex says that the U.S.

10:13:42 Memorial did not claim that Apotex had failed to show any State practice showing that States provide hearings and other procedural protections before refusing admission of adulterated drugs.

Let me again read from Paragraph 366 and 367 of our Counter-Memorial--this is the United States argument--Apotex contends that "international law requires due process in administrative decision making concerning specific persons."

Apotex contends in particular that before a State may stop adulterated drugs from entering into its territory, customary international law requires that it provide the exporter: One, a hearing; two, with advanced notice; three, before an impartial decision maker; four, at which the exporter may present evidence and contest a decision; and, five, obtain a reasoned decision relying on all relevant legal and factual considerations; and, six, affording judicial review of the validity of any decision.

Paragraph 367, Apotex offers no relevant State practice for this extraordinary proposition. As the Glamis Tribunal recognized, "Ascertaining custom

10:15:03 is necessarily a factual inquiry looking to the actions of States and the modus for and consistency of those actions."

This factual inquiry can be undertaken using a variety of sources, such as citations to statutes, regulations, or case law. Here Apotex has introduced no statutes, regulations, or case law as reflecting State practice to establish its proposed new rule of customary international law.

Again, we submit that the United States clearly addressed this point in our Counter-Memorial. It is not appropriate for Apotex to have introduced new Legal Authority one business day before the hearing to begin.

Point three, Apotex says that all of the new Legal Authority submitted on Friday go to these two arguments. As Apotex mentioned, however, it has prepared for the United States this morning a summary of its new Legal Authority. The first Legal Authority itself is not consistent with that statement. CLA-631, the UNCTAD pamphlet on Most-Favored-Nation Treatment.

10:16:13 I'll read Apotex's representation of this. (A), in Paragraph 369 of its Rejoinder, the U.S. asserts that "Apotex has not met the basic requirement of Article 1103 to identify a comparator in like circumstances."

(B), Claimants seek to rely upon pages 63 and 64, which demonstrate there is no requirement to identify a specific comparator."

Clearly this new Authority is not limited to the supposed new arguments that the United States made in its Rejoinder. These arguments were not new. They were entirely appropriate. And we submit that the Tribunal should not accept these Authority which do not--which could have been submitted with this Reply.

Thank you. Ms. Grosh.

PRESIDENT VEEDER: I'm sorry to interrupt you, but that's quite helpful. You've gone through that first comment as regards CLA-631.

Is it worth our knowing what's being said about the other new Legal Authority, 632, 633, 634, and 635?

MR. SHARPE: Before my colleague, Ms. Grosh,

10:17:26 concludes with a few general points, if I might just note that Apotex has introduced two provisions of the French legal code that presumably purport to relate to the requirements of a State before a denying importation of the adulterated drugs.

Obviously, the United States is not represented by French counsel. United States made these points in the Counter-Memorial about how a Claimant might go about establishing a State practice in this regard. And as we note in our letter, we think it is entirely unfair to expect the United States to respond to French Legal Authority in a short amount of time. We're not French lawyers. One might have to look at French law in relation to European Union law and so forth. So that we also submit should be excluded.

The other documents do appear to go to the points that were raised by Claimants' counsel this morning on Article 1105, but as I suggested, the United States made our arguments on 1105(1) in our Counter-Memorial and, therefore, although these documents do go to that point, they should have been,

10:18:32 we submit, fairly raised with Apotex's Reply rather than at the hearing.

PRESIDENT VEEDER: I'm sorry to press you, but it's important for us to get clear what's in issue.

637 and 638 have been taken off the table.

MR. SHARPE: Correct.

PRESIDENT VEEDER: So we can forget about those.

The French legislation is 634 and 635.

MR. SHARPE: That's correct, my understanding, right.

PRESIDENT VEEDER: Now, you've addressed us on 631 as regards the purpose for which Apotex is seeking to put in this Authority. Is it worth your going through 632 and 633?

MR. SHARPE: 632 is the Siemens versus Argentina decision on jurisdiction. This, as Apotex has informed us this morning, would be used to address the issue of Article 1105(1).

CLA-633 is Plama versus Bulgaria, also the decision on jurisdiction, and this is also represented

10:19:33 to go to Article 1105(1).

634 and 635 are the French Legal Authorities.

636 is Al-Bahloul versus Tajikistan, a Stockholm Chamber of Commerce Case from 2009. And this also is stated to go to Article 1105(1).

The final two cases are the European Court of Human Rights cases that we understand were withdrawn today.

PRESIDENT VEEDER: Thank you very much.

MS. GROSH: Mr. President, I would like to just make a few concluding remarks about the new documents as well. And that is that this is, again, a matter of procedural fairness. And normally when Tribunals look at whether to accept new submissions like this, new filings so close to the hearing, they look at, Number 1, prejudice to the other Party, whether there has been any justification whatsoever at why these materials have been produced at the late date, and also the integrity of the proceedings.

Now, Claimants' counsel referred to a very tight briefing Schedule, and I would submit that no Party in this proceeding has been impacted more than

10:20:52 the United States by this very, very tight briefing schedule, and in particular, occasioned by the enormous production of documents that Claimant imposed on the United States. So, in large part, this has been driven--the tight briefing Schedule has been driven in large part by the Claimant.

So here we are, Friday, the eve of the hearing, and we are in receipt of documents. There has been no justification why they were provided at this late date. Either in connection with, as Mr. Sharpe alluded to, many of these arguments were, in fact, made by the United States in the Counter-Memorial, and the date of these particular provisions or Awards suggest that they could have been provided at a much earlier date with the Claimants'--at least with the Claimants' Reply.

Second of all, I would just note that this Tribunal had a procedural meeting on October 31. We discussed production of the Hearing Bundles. There was no suggestion whatsoever that the Claimant was considering additional documents or authorities that it wanted to introduce. The United States and

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Claimant have been in regular phone contact in putting together the bundles and addressing any number of procedural issues to be ready for this hearing, and not during one of those calls or during any of the e-mails was there any suggestion whatsoever that new materials were going to be provided at such a late date.

So, again, we believe that this is a matter of fundamental fairness and, in fact, we find it rather incredible that the Claimants' counsel would have referred to sandbagging in this case because I think there is no question, really, which Party has been sandbagged through this process.

Thank you very much, Mr. President.

PRESIDENT VEEDER: There is one question for you. Do you envisage the possibility--I don't say the present intent--of submitting to the Tribunal any new legal materials during this hearing?

MS. GROSH: Mr. President, we haven't envisioned that, but it depends in large part whether these materials would be introduced by the Tribunal or not. They are very voluminous. I think it is telling

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that the Claimant felt the need to provide us with what amounted to a four-page essentially legal submission on what these Authorities are going to be relied on, and if they were to be submitted, I think we would have to have the opportunity to address them in the way that we would see fit.

But again, our first and foremost request is that they not be admitted. Thank you.

MR. SHARPE: Nothing further from the United States, Mr. President.

PRESIDENT VEEDER: Thank you very much for the Opening Statement. Let's take a break, now, for 15 minutes. We'll come back at 20 to 11:00 and we will continue with the hearing at that stage.

(Brief recess.)

PRESIDENT VEEDER: Let's resume. Before we give the floor to the Claimant, we'd like to address three of the disputed applications on which the Parties completed their submissions earlier this morning.

As regards the time for the Closing oral submissions, we're going to keep that under reserve,

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and we'd like, later this week--but obviously long before the end of this week--come back to you with a possibly proposal, depending on events between now and then. So we'll park that application for the time being.

As regards the Legal Authorities recently submitted by the Claimant into the file, we are going to allow that application, but subject to these caveats.

It applies to the Legal Authorities 631, 632, 633, 636. It does not apply to the two authorities withdrawn, 637 and 638. Those two will be removed from the file. We have experienced some hesitation in regard to the French text, that is 634 and 635.

We're going to let in those materials, but we are not giving a blank check to the Claimant. So how they deploy these materials remains something of a mystery to us, and if they go beyond their pleaded case, then obviously the Respondent can make an objection. But the materials come in, and we'll see where they go.

The other application is the application by

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the Claimant to strike part of the pleading and the evidence submitted by the Respondent. As in every arbitration when we look back, we can see how it could have been done better and differently, and we understand the difficulties which the Claimant has faced in addressing these materials late in the written phase of these arbitration proceedings. But we decide to let in these materials. Again, if the Claimant were to suffer prejudice, we'll listen to that complaint, but at the moment, we are not persuaded that there has been any or sufficient prejudice suffered by the Claimant that would require us to exclude these materials. So they are admitted into the file.

So, those are our rulings. Unless there is any more housekeeping material we need to look at, we'll give the floor to the Claimant for their full Opening.

MR. LEGUM: Thank you, Mr. President. I will just address one aspect of the presentation that we'll give before turning the floor over to Mr. Hay to address the facts of this case.

10:46:40 In terms of dealing with confidential information--and there is a fair amount of confidential information in this case--what we have done to the maximum extent possible is to redact the slides that will be shown so that you will see slides that have certain aspects like product names redacted, but that will allow us to continue, and to continue the broadcast to the other room without interruption.

Obviously, the Tribunal has the full unredacted copies that are in the record.

With respect to our presentation on the facts, however, there will be a portion of that that will address confidential materials to such a continuous extent that we will ask the feed to be cut. And Mr. Hay will, obviously, make that clear when that needs to be done. But that should be the only presentation where we need to cut the feed.

Thank you, Mr. President.

PRESIDENT VEEDER: Thank you.

MR. HAY: Good morning, Mr. President, Members of the Tribunal. I am John Hay, and this morning I'm going to talk about the facts of the case.

10:47:50 I will highlight the salient facts in order to provide the Tribunal some context to the legal issues that will be discussed subsequently.

First, I will provide some background information concerning the Claimants. Second, I will provide a brief overview of FDA Regulatory Framework relevant to the issues in the case. And, finally, I will discuss the chronology of events that led to this arbitration.

Turning to the Claimants.

Claimant Apotex Holdings is a privately held Canadian company. It's the largest Canadian seller of generic pharmaceuticals. Apotex Holding is the holding company for the Apotex Group of companies. The Apotex Group consists of companies formed and operated in Canada, the United States, and throughout the world.

The business plan of the Apotex Group is one of vertical integration. By that I mean the Apotex Group performs all of the necessary steps of generic drug development, manufacturing, approval, marketing, and distribution through the worldwide group of

10:49:06 companies. Through this vertical integration business model, the Apotex Group is able to increase its efficiency and profitability.

Apotex Holdings indirectly owns and controls Apotex Inc., a Canadian company, which I will refer to as Apotex-Canada. Apotex-Canada serves as the development and manufacturing arm of the Apotex Group. Apotex-Canada operates three manufacturing and R&D facilities in Canada--Etobicoke, Signet, and a third facility, Richmond Hill, which is not the subject of this arbitration. Both Etobicoke and Signet produce solid oral dosage forms of generic drugs, such as tablets and capsules.

Apotex Holdings also indirectly owns and controls Apotex Corp., a U.S. company, which I will refer to as Apotex-U.S. Apotex-U.S. was set up to be the distribution and marketing arm of the Apotex Group in the United States. Apotex-U.S. is a Delaware corporation. It is the U.S. investment of Apotex Holdings.

Apotex-U.S. was the sixth largest seller of generic drugs in the U.S. before the Import Alert was

10:50:30 adopted. Two years later, it was the 25th largest. In 2009, Apotex-U.S. relied on Apotex-Canada for 80 to 85 percent of the generic drugs it sold in the U.S.

It is undisputed that Apotex Holding is an investor, and that Apotex-U.S. is the investment--is its investment under the NAFTA. Apotex also maintains that Apotex-Canada is also an investor, and as its investment, it holds numerous Marketing Authorizations that enable it to manufacture the products that Apotex-U.S. sells in the United States. Apotex Holdings also holds, as its investment, the marketing authorizations owned by Apotex-Canada because it indirectly owns Apotex-Canada.

I will now discuss briefly FDA's Regulatory Framework and the procedures as provided under U.S. laws and regulations that relate to this dispute. I will discuss the authorization to market drugs in the U.S.; the inspection and review process that applies to facilities manufacturing drugs for sale in the U.S.; and, finally, the various enforcement tools that FDA has.

To market drugs in the United States, a drug

company must obtain a Marketing Authorization from FDA. This is commonly known as an ANDA, which stands for Abbreviated New Drug Application. Although this term applies to both the application for and the finally approved Marketing Authorization, in this arbitration we will use the term to denote the finally approved Marketing Authorization unless otherwise indicated. At the time of the Import Alert, Apotex had 153 Marketing Authorizations for sale of drugs in the United States.

Marketing Authorizations are site specific; meaning that the site used for testing and manufacturing the drug must be described in the application for Marketing Authorization and approved by FDA.

Once FDA has granted the Marketing Authorization for a specific site, the site cannot be changed without FDA approval. Drugs cannot be sold in the U.S. unless they have been manufactured by a facility identified as the site for the applicable Marketing Authorization.

Apotex-Canada could not have manufactured

drugs for the U.S. market without its Marketing Authorizations. Equally, Apotex-U.S. could not have sold the drugs provided by Apotex-Canada if Apotex-Canada did not have these Marketing Authorizations.

ARBITRATOR ROWLEY: Right, am I, that when you refer to the 153 Marketing Authorizations, that they are Marketing Authorizations owned by Apotex-Canada as opposed to Apotex Holdings?

MR. HAY: Apotex-Canada; correct.

Marketing Authorizations can only be used in the United States. The application is prepared and filed with the FDA with a view to distributing the drug in the U.S. market and not anywhere else. That said, because the U.S. is the largest pharmaceutical market in the world, the U.S. market dictates many of Apotex's decisions on which products to develop. Apotex primarily targets the U.S. in its product development strategy.

The slide currently before you summarizes these points. As it indicates, Apotex Holdings indirectly owns Apotex-Canada and Apotex-U.S.

Apotex-Canada sells products to Apotex-U.S. for sale in the U.S., and through the Marketing Authorizations, Apotex-Canada can manufacture drugs for sale in the U.S., and Apotex-U.S. can actually sell the drugs in the U.S.

FDA inspection pharmaceutical manufacturing facilities to check for compliance with current good manufacturing practices, termed "cGMPs." FDA establishes cGMP standards by promulgating regulations in the Code of Federal Regulations that manufacturers must adhere to. These cGMP standards address the proper design, monitoring, and control of manufacturing processes at facilities.

The cGMP regulations are very general and infrequently updated. Instead, FDA provides guidance documents to provide some detail as to what are current good manufacturing practices.

The general nature of the regulations afford a significant amount of discretion to inspectors who inspect the facilities to determine cGMP compliance.

Under U.S. law, a drug is considered adulterated if the methods or facilities used to

produce it do not conform to cGMP so as to ensure the safety, identity, strength, and purity of the drug. However, FDA has made clear that drugs that are deemed difficulty trade because of cGMP deviations may still fully meet specifications and be safe and effective.

The slide on the screen is a statement from the FDA Web site which explains this point. Of particular note it says that "If a company is not complying with cGMP regulations, any drug it makes is considered adulterated under the law. This kind of adulteration does mean that the drug was not manufactured under conditions that comply with cGMP. It does not mean that there is necessarily something wrong with the drug."

FDA principally assesses conformity with cGMP through on-site inspections of drug manufacturing facilities. FDA performs inspections of both domestic and foreign drug manufacturing facilities. At the end of the inspection--if, at the end of the inspection, the investigators believe they have identified cGMP deficiencies, they record their observations on a Form 483, which is immediately given to the inspected

company.

Basically, the Form 483 is what the investigator thinks is wrong. It serves to notify both FDA and the firm of specific cGMP deviations that need to be corrected. However, the Form 483 explicitly states that it only represents the inspector's observations and that it does not represent a final agency determination regarding the firm's compliance.

After receiving the 483, the firm then has the right to respond to the listed observations. The firm can either provide clarification as to why the investigator may have been wrong or it can propose corrective action.

After the inspection, the investigator also writes up an Establishment Inspection Report, or EIR. The EIR and 483 are normally subject to two levels of further review: First, the investigator's superior and then the relevant FDA center. The EIR is not shared with the company at the time of the inspection.

After reviewing the company's response to the Form 483, FDA may--or may not--decide to issue a

Warning Letter to the inspected company. Warning Letters serve two functions: First, they put the company on notice that serious deviations from cGMPs were observed and must be corrected promptly, or FDA may take enforcement action. Second, they give the company an opportunity to explain and to voluntarily take corrective action after being told exactly what FDA believes is wrong with its practices.

Because the 438 is only the investigator's observations, it is not until the company receives a Warning Letter that it is actually advised of FDA's official position.

If FDA decides to issue a Warning Letter, the recipient company has an opportunity to respond within 15 days to the Warning Letter. FDA will evaluate the Response to the Warning Letter. If FDA considers the response to be inadequate, FDA can decide to take follow-up action as necessary to achieve correction, including some form of enforcement action.

FDA regulations allow for it to take more severe regulatory actions before issuing a Warning Letter in certain limited circumstances. The U.S.

acknowledges that this is the case only when issuing a Warning Letter would either be unnecessary because the company's conduct is repeated, continuing, flagrant, intentional or criminal, or it would be inappropriate to use a--to issue a Warning Letter because there are exigent circumstances, such as when there is a reasonable possibility of injury or death.

I will now turn to FDA's potential enforcement actions. First, FDA can seize product in violation of the Act--products that are in violation of the Act that are in interstate commerce. Seizure actions proceed against the actual drug so FDA has in rem jurisdiction over all drugs that violate the Act located in the U.S. In order to seize a violative product, FDA must file a seizure action in Federal District Court against the product. Then the product can be seized under a warrant issued by the Court. This type of action requires the independent approval of a federal judge.

Second, FDA can enjoin the manufacturer from making products in violation of the Act or the distributor from distributing such products. FDA has

authority to enjoin manufacturers with respect to facilities both in and outside the United States. Again, this action must be independently reviewed and overseen by a federal judge.

Third, FDA can issue an Import Alert for imported products only. FDA can issue the Import Alert if it has evaluated samples of the product and determined that the product violates the Act, or it can issue an Import Alert if it deems that the drug appears adulterated, usually based upon a site inspection of the manufacturing facility. If articles are manufactured in facilities what cGMP deficiencies are observed, then these products are deemed adulterated by FDA. Those drugs may be refused admission.

The Import Alert is the document that FDA issues to inform the officers at customs that certain imports should be refused. This is referred to as Detention Without Physical Examination, DWPE, or automatic detention. As stated on the Import Alert, once a company is placed on Import Alert for cGMP violations, its products will be automatically

detained until the FDA confirms that the company is cGMP compliant, which usually is done during a reinspection.

Finally, the FDA has authority to punish severe violations of the law through criminal penalties, which would include imprisonment and criminal fines.

Now I'm now going discuss the relevant specific facts of the case.

ARBITRATOR ROWLEY: Just before you go there, a little while ago you said no Warning Letters need be issued if the conduct is repeated, continuing, flagrant, intentional or criminal or if there's a reasonable possibility of injury or death.

Is that set out somewhere in the enactment or regulation, or is that part of the practice?

MR. HAY: It's part of the procedures manual. And it's--CLA-305 is the cite to the record.

MR. LEGUM: Just a quick note, on the slides, we've tried as much as possible to include specific references to the record. So on the slide that contained that, it should be--admittedly, in somewhat

small print--the specific record reference.

PRESIDENT VEEDER: In this one you referred to Paragraph 255 of the Respondent's Rejoinder, where this is set out. So this seems to be common ground.

MR. HAY: Okay. As I started to say, since I'm going to be talking about the specific facts as Mr. Legum mentioned, this is a portion of the presentation in which Apotex products, manufacturing processes, and other confidential information will be discussed. So we would request that the video feed be cut and that this portion of the presentation be deemed confidential.

PRESIDENT VEEDER: Just before we proceed, who is checking that the feed is cut?

Please confirm on the transcript when it's cut and resumed. So we'll ask you to confirm that it has been or will be cut.

SECRETARY TAYLOR: I'm confirming that the broadcast has been cut to the public hearing room until we are otherwise informed by Claimants' counsel.

CONFIDENTIAL PORTION

MR. HAY: Thank you.

Okay. Apotex-Canada, as a Canadian drug manufacturer, is primarily regulated and controlled by Health-Canada. Its facilities have been regularly inspected by Health-Canada since the mid-1970s. In addition, since Apotex-Canada supplies the U.S. drug market, its facilities have been periodically inspected by FDA.

Apotex's Etobicoke and Signet facilities have been inspected multiple times by FDA from 2000 to 2007 without incident. We detail this prior inspection history at pages 39 and 40 of our Memorial--I'm not going to repeat it here. We will say that most recently before the inspections at the issue here, after its inspection of Signet and Etobicoke in 2006, FDA issued two Form 483s.

After Apotex provided further written information to FDA in response to those 483s, these two facilities were deemed acceptable by FDA. Prior to the Warning Letters issued in 2009 to Etobicoke and, in 2010, to Signet, Apotex had never received a

Warning Letter from FDA.

From December 10-19, 2009, FDA inspected Apotex's Etobicoke facility. The inspectors were assigned to conduct a cGMP inspection as well as a preapproval inspection, or PAI, for nine ANDAs. FDA sometimes conducts PAIs before making a recommendation as to whether or not to approve an ANDA.

According to the U.S., FDA requested a direct or "for cause" inspection of the Etobicoke prompted by consumer complaints received concerning the lack of efficacy of the Apotex drugs Carbidopa-Levodopa.

Apotex's Etobicoke site was inspected by two inspectors, a Ms. Emerson and a Ms. Campbell. During these inspection, the inspectors performed a cGMP inspection and several paper PAIs and reviewed and evaluated the reports and investigations concerning Carbidopa-Levodopa.

At the close of the inspection, the inspectors issued a three-page 483 listing 11 observations on a variety of issues.

On January 30, 2009, Apotex-Canada responded in writing to the inspectors' 483 observations and, at

11:08:52 the same time, Apotex immediately undertook to enhance its processes and equipment at Etobicoke.

On May 8, Apotex decided to check in with FDA because it hadn't received any information about its response to the Etobicoke 483. Apotex wanted to know whether its response was adequate and addressed FDA's concerns. Dr. Carmelo Rosa replied that FDA was still evaluating the inspection and Apotex would receive a response when the evaluation was complete.

Now, I want to shift focuses to what was happening at FDA during the months after the Etobicoke inspection.

Initially, it should be emphasized that Apotex did not know these facts that I'm about to recount. It heard nothing from FDA. Apotex only learned of what FDA was thinking and doing during the January to August 2009 time period through disclosure in this case.

First, the good news. By early February 2009, FDA inspector Emerson had completed her Report on Carbidopa-Levodopa. You will recall that issues concerning that drug were raised and--were the

11:10:24 cause of the inspection--the for-cause inspection. Those issues were also the subject of certain 483 observations, and were addressed by Apotex in its January 30, 2009, response to the 483.

In her Report, Ms. Emerson stated that she found no issues in any of the materials that she had reviewed during the inspection, that all complaints reviewed were appropriately investigated and documented, and no negative trends were seen. That ended the issue at the time, and this issue was not even mentioned in the Etobicoke Warning Letter, which I will discuss in a few minutes.

Unfortunately, that was the extent of the good news from Apotex's perspective.

Now, the bad news. As an initial matter, it is important for the Tribunal to understand FDA's change in enforcement approach that was being implemented at the time. As detailed in Apotex's pleadings and referenced by Mr. Legum in his Opening Statement, in 2009, new FDA Commissioner Margaret Hamburg announced a new enforcement strategy called "Effective Enforcement," which included sending a

11:11:35 strong message by publicizing the use of major sanctions against at least one alleged offender. She stated that the FDA needed to be vigilant, strategic, quick, and visible.

This new focus should be kept in mind when considering FDA's conduct vis-à-vis Apotex. It is clear that FDA chose to make Apotex an example of FDA's tough new policy, even though its treatment of Apotex was completely unjustified.

Now, turning back to the chronology, two things are clear from the contemporaneous documents produced by the U.S. in this matter.

First, as early as the April to May 2009 time period, FDA had already prepared and circulated within FDA drafts of the Etobicoke Warning Letter and was already contemplating an Import Alert.

Then, on June 7, 2009, the Director of CDER Office of Compliance, Deborah Autor, advised CDER Director Janet Woodcock about the impending Etobicoke Warning Letter. In so doing, Ms. Woodcock was provided with copies of the 483 and EIR for the Etobicoke inspection. However, at the time,

11:13:00 Ms. Woodcock was told that the 483 and EIR were basically irrelevant as regards the Warning Letter because the issues upon which the Warning Letter was based had been identified not by the inspection but instead by people at CDER based on their review of certain documents.

Ms. Woodcock was also sent a draft Warning Letter and a memo, which included a list of "key issues," which provided background information for the proposed Warning Letter.

The next day, Ms. Woodcock responded by saying that Apotex should not be shipping drugs in the U.S. and asking what FDA planned to do besides issuing a Warning Letter.

Upon receipt of this e-mail, the Director of Compliance immediately asked her team to do an Import Alert sooner rather than later. Apparently, the only thing that held up an Import Alert then was the fact that a drug shortage determination had not yet been completed.

On June 1, FDA had asked for information concerning possible drug shortages in order to assess

the impact of regulatory action against Apotex and, in fact, certain information in this regard was circulated within FDA on June 18. Due to the large market share of many of Apotex's products, FDA decided to hold off on an Import Alert for the moment.

That said, clearly at that point in time, the die was cast. This exchange between Ms. Woodcock and her staff was based upon a Key Issues memo that was hastily prepared before FDA completed its analysis of information concerning Apotex, information that Apotex had no opportunity to address or explain, which, as I will describe now, was infected by baseless assumptions and--baseless suspicions and mistaken assumptions.

These suspicions and assumptions did not arise from the Etobicoke inspection, and they were not raised in the Etobicoke 483. Rather, they arose based on FDA's misunderstanding of data and other information from Apotex which FDA never discussed with Apotex until after the Warning Letter and Import Alert.

First, FDA received two consumer complaints

in 2009 related to the mixup of different strengths of a drug, Leflunomide tablets, and the size of one Tramadol tablet. Those complaints were investigated by FDA, including searching adverse reports and doing some samplings. No issue was ever raised with Apotex about those. For its part, Apotex, unaware of FDA's investigation of those issues, independently investigated the complaints and found them to be isolated incidents that posed no health risk.

Second, in a summary of the Apotex case prepared by FDA's Apotex case officer, Ms. Molina, FDA mistakenly assumed that Apotex had withdrawn multiple ANDA applications because it was not ready for inspection. This same case officer drafted the Warning Letter based on this summary.

In sum, Apotex had withdrawn certain bundled supplements that added Signet as an alternative testing site. These were withdrawn to streamline and simplify the approval process, having nothing to do with the readiness for inspection. However, FDA apparently assumed that the withdrawals were based upon the site not being ready. Since FDA never raised

the issue with Apotex, Apotex could not correct FDA's misimpression. The issue was also included as part of FDA's "key issue" memo to justify Etobicoke Warning Letter.

Third, FDA misunderstood the Apotex data concerning rejected batches, which FDA thought appeared high and suggested that Apotex's manufacturing practices were out of control. This issue of "rejected batches" was one of the primary justifications for the Etobicoke Warning Letter as set forth in the key issue memo.

However, at the Etobicoke inspection, the investigator requested a list of rejected batches, but never reviewed the data. It was not an observation on the 483, and Apotex never had the opportunity to explain the data or address any concerns that FDA might have until the issue surfaced for the first time in the Etobicoke Warning Letter.

Fourth, the same FDA officer had raised the unwarranted concern--that raised the unwarranted concern about the withdrawal of the ANDAs also mistakenly thought that Apotex was part of the Teva

Corporation. One of Teva's subsidiaries, Novopharm, had recently been inspected and had similar violations to Etobicoke.

From this, the FDA officer mistakenly concluded that there may be a corporate-wide problem. So he forwarded this information to the Apotex case officer within FDA so she could use it in her review of Apotex. Unfortunately, the case officer also did not check her facts regarding Apotex's corporate structure, because similar cGMP violations had been observed at Etobicoke and Novopharm, two facilities that she thought were the same corporation, she concluded that FDA's goal should be a corporate-wide Warning Letter.

Fifth, FDA did not analyze or verify its data on Adverse Event Reports. Aside from suffering from the same flaws as the rejected batch list; that is, that this information really included merely raw counts and did not give any underlying information, Adverse Event Reports were also not covered in the inspection, so Apotex neither was informed of this nor had a chance to address them. Yet it was included in

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11:20:17 the Key Issue Memo that formed the basis for Ms. Woodcock's directive that Apotex should not be selling drugs to the United States.

Even though Apotex's response to the 483 was on January 30, 2009, the next word from FDA concerning Etobicoke came on June 25, 2009, about five months later, when FDA issued a Warning Letter concerning Etobicoke. The Warning Letter cited only two cGMP violations, along with the failure to file Field Alert Reports on time, which is not a cGMP issue but is often addressed with cGMP violations.

The first item in the Warning Letter concerned the rejected batches list that CDER had independently uncovered. FDA cited Apotex for failure to investigate these rejected batches.

As previously mentioned, during the Etobicoke inspection, the investigators did not request Apotex's investigations of rejected batches. This concern was not included on the 483. It had never been communicated to Apotex. The first time Apotex found out that FDA was concerned with its investigations into rejected batches was in this Warning Letter.

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11:21:53 Apotex was being cited for a violation that it had no prior notice of and no chance to respond to.

When Apotex had a chance to respond to the issue in its response to the Warning Letter, Apotex included an explanation of the 554 batch rejections. Apotex noted that not all rejections are indicative of process-related concerns. [redacted]

FDA was also concerned that Apotex had released rejected batches to the U.S. [redacted]

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11:23:17 In its response to the Warning Letter, Apotex provided detailed documentation showing that the rejected batches and the distributed batches were not the same. Apotex provided supporting documentation showing that the rejected batches were destroyed and not used to manufacture any other batches. It also provided analysis of the shipped batches, showing that these batches were not manufactured using batches that had been rejected.

This response proved that FDA's suspicions were wrong, but it was not reviewed prior to FDA implementing the Import Alert.

As demonstrated on the screen, FDA had misunderstood Apotex's batch numbering system and confused the numbers of batches that had been rejected with the number of batches that had been released.

Apotex then provided an analysis of all products specifically mentioned in the Warning Letter, and in one case told FDA that it no longer had the intention of manufacturing that product because it was no longer commercially viable.

In response to FDA's concern regarding

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11:24:30 cross-contamination of one drug, [redacted]

Apotex believed that its responses and evidence it provided in support of that response demonstrated that it conducts through investigations of out-of-spec results and that these investigations extended to address other potential affected batches, which was the first stated concern of the Warning Letter.

The second item listed in the Warning Letter concerned the late filing of Field Alert Reports, or FARs. It is curious that the Warning Letter included a reference too late filing FARs, since in response to the 483, Apotex had implemented corrective action addressing this issue, and FDA had determined that

this corrective action was adequate. In any event, Apotex also provided a table of FARs filed in 2009 to illustrate that it was currently meeting the three-day time requirement.

For the third and final issue listed, Apotex explained its electronic labeling process, which eliminated the need for keeping a physical sample of the approved label in the batch record. Apotex was hopeful that FDA would accept its response, but in any event--but in the event that FDA disagreed with Apotex's electronic system, Apotex committed to include a copy of each label as part of the batch record.

FDA currently accepts Apotex's practice of keeping electronic copies of labels.

On August 4, two weeks after Apotex supplied its response, Apotex contacted FDA to follow up on that response. Apotex requested a meeting to ensure that its response and actions were addressing FDA's concerns and possibly to determine additional actions that were required. FDA didn't respond to this request until the morning of August 17 telephone

conference, which I will discuss in a few minutes.

On August 12, Apotex again contacted FDA to request a meeting to go over the Response to the Etobicoke Warning Letter. This was the first Warning Letter Apotex had ever received, and it was important to Apotex to resolve it properly. FDA replied that it would review Apotex's request and return a decision soon.

Now, I'm going to move on to the Signet inspection, which started on July 27 and lasted through August 14. In contrast to the Etobicoke inspection, FDA utilized two--not only two experienced inspectors from the district office, but also two compliance officers from CDER. In addition, there was a significant amount of communication between the CDER inspectors and the personnel at CDER office throughout the inspection.

The lead CDER investigator sidetracked the lead investigator, Mr. Payne, and took a combative approach, and, unlike typical FDA inspections, allowed Apotex only limited opportunity to provide explanation concerning her findings.

During the inspection, FDA's Mr. Martinez contacted the inspection team to discuss an Import Alert and before the closeout of the inspection on Wednesday, the CDER lead inspector had already transmitted a draft 483 that they admittedly thrown together so FDA could get started on the Import Alert. This draft 483 did not contain observations from the district inspectors. The next morning on Thursday, Dr. Rosa instructed the Apotex case officer to update the draft of the Import Alert, which she did that very same day.

On Friday, August 14, FDA's inspectors issued a 483 concerning the inspection with 17 observations. The bulk of these concerned failure to timely submit FARs, the failure to complete written records, and the failure to follow written procedures. The 483 also noted that defective batches, although rejected, were not sufficiently investigated and documented.

Also on Friday, at the end of the Signet inspection, Apotex was instructed to contact CDER to provide its next steps. This call took place the next business day at the close--after the close of the

inspection. Apotex had only two days to review the observations listed in the 483. This was obviously not enough time for Apotex to prepare detailed Corrective Actions or seek expert advice.

Nevertheless, on Monday, Apotex contacted FDA to schedule a one-hour conference call for 2:00 p.m. that day. During this call, Apotex volunteered to recall certain batches of drugs that were identified as of a concern to FDA. Apotex also informed FDA that it had already begun to implement Corrective Actions, including hiring outside consultants to assist it with its processes. Apotex was reacting as quickly and meaningfully as possible to the FDA observations given the limited time since receiving those observations.

But as Apotex later came to discover, FDA long ago had decided to go ahead with the Import Alert.

At 3:21 p.m. that day, Dr. Rosa returned the draft Import Alert recommendation memo to the FDA case officer after he had reviewed it and asked her to include more issues raised in the Etobicoke Warning Letter and the Signet inspection.

Consistent with FDA's newly announced policy of quick and visible action, Dr. Rosa noted that FDA "was against the clock."

The Apotex case officer returned the draft recommendation to Dr. Rosa incorporating his comments at 5:00 p.m. that day. On the screen is the draft Import Alert memo dated August 17, 2009.

The day after the telephone conference, on Tuesday, August 18, CDER's weekly internal memo, the Sharfstein report, stated CDER's decision to go forward with the Import Alert. This document also makes clear that FDA had not yet completed review of Apotex's response to the Etobicoke Warning Letter. FDA was going ahead with the Import Alert without reviewing all available evidence.

It is also noteworthy that the Report has a field for "known/suspected injuries," which was blank, indicating that there was no known or even suspected injuries that resulted center use of Apotex's drugs.

On August 24, in line with the Commissioner's pronouncement, before the Import Alert had been officially implemented, FDA was already publicizing

its efforts. A high-ranking FDA official in a widely-attended industry conference disclosed the imminent regulatory action emphasizing FDA's swiftness, but without naming Apotex.

On August 25, the Import Alert recommendation memo was sent to the Division of Import Operations and Policies, or DIOP. It is noteworthy that FDA was telling the word on August 24 that regulatory action was imminent, and yet the Import Alert memo had not even been sent to DIOP at that point.

On August 28, Dr. Rosa e-mailed DIOP inquiring about the status of the Import Alert. He requested to be told as soon as the Import Alert was in effect. DIOP issued the Import Alert less than 30 minutes later.

Shortly thereafter, FDA's Mr. Martinez informed his superiors that the Import Alert was in place, again emphasizing the swiftness of FDA's action.

That same day, Apotex sent FDA a description of its Corrective Action Plan and had a telephone conference with FDA to discuss the voluntary recall.

During that call, there was no mention by FDA of the Import Alert. In its letter to the FDA on that day, Apotex listed all of the actions it had completed in response to FDA's observations. [redacted]

To show its serious innocence addressing FDA's concerns, Apotex committed to cease distributing certain additional products pending the completion of a through root cause investigation and implementation of corrective action.

Apotex had retained consultants to review its past practices, to oversee its current practices, to perform--and to perform a comprehensive quality systems audit, and also to develop a Corrective Action Plan to ensure robust and sustainable quality systems and that they would apply globally.

On Apotex also expressed its commitment to ensure that necessary action would be taken to address FDA's concerns. Apotex submitted this letter before it was aware that it was placed on Import Alert. FDA

had already placed Apotex on Import Alert by this time, by the time it received and reviewed this letter.

On September 2, further demonstrating its commitment to FDA, Apotex initiated its voluntary recall. FDA classified this recall as a Class II recall, meaning that the probability of serious adverse health consequences was remote. That FDA believed that Apotex's products did not pose a serious risk is also evidenced by the fact that FDA took no action against Apotex's products already in the U.S. market.

That same day, September 2, Apotex learned about the Import Alert that was taken against it. However, it learned of the Import Alert not from FDA, but instead on a call with Health-Canada.

On September 3, Apotex submitted its 42-page response to the Signet 483 observations. Firms are entitled to 15 business days from receiving the Form 483 to respond to each of the observations in writing, and Apotex complied with that timetable. It didn't matter. FDA imposed the Import Alert before Apotex

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had an opportunity to respond to the investigators' observations.

Also on September 3, Apotex requested an urgent call with FDA to discuss the Import Alert. In that call, Apotex was first advised by FDA of the Import Alert. When Apotex requested the reasons for the Import Alert, FDA's Mr. Martinez explained to Apotex that because Etobicoke had received a Warning Letter and significant cGMP violations were found during the Signet inspection, an Import Alert was appropriate. This is the only justification for the Import Alert that Apotex would receive. During the call, FDA emphasized that the Import Alert would only be ended upon successful reinspection.

On September 8, the CDER recall shortage coordinator asked Dr. Rosa and others at FDA if Apotex had been added to the Import Alert list and for a list of products that were affected. The e-mail exchanges make clear that FDA had no current list of Apotex drugs to allow them to determine the extent of the risk of drug shortages. Consequently, FDA issued the Import Alert against Apotex without a full and proper

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evaluation of the effect it would have on the U.S. pharmaceutical market. It was also aware that for certain products, Apotex's market share was significant.

On September 11, Apotex again met with FDA to discuss corrective action. During this meeting, FDA acknowledged that it still--that it had still not yet reviewed Apotex's response to the Signet 483, which detailed many corrective and preventive actions. At the meeting, FDA committed to provide Apotex with timely feedback. Instead, Apotex waited months to hear back from FDA on various protocols and reports it submitted. Most importantly, FDA made clear to Apotex yet again that the only way to remove the Import Alert was through successful reinspection. Dr. Rosa also made clear that FDA would not inspect Apotex into compliance.

Now, at that time, other regulatory agencies around the world got word of the FDA Import Alert with respect to Apotex. An Import Alert is obviously a very serious regulatory action. Understandably, this worried the other regulators and--about Apotex's

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products. At that time, Apotex reached agreements with the public health authorities in the EU, New Zealand, and Australia, to voluntarily, temporarily suspend sales of Apotex's products until Health-Canada completed its review of Apotex's facilities. These voluntary suspensions were precautionary and not based on any independent evaluation of Apotex's facilities by those authorities; rather, they were solely based on the FDA Import Alert. Those suspensions ended quickly when Health-Canada deemed Apotex's facilities cGMP compliant.

For its part, Health-Canada immediately began an intense inspection of Apotex's Etobicoke and Signet facilities. The inspection lasted many weeks. Ultimately, Health-Canada concluded that while Apotex's manufacturing processes could be improved in ways that Apotex was already addressing, both facilities were cGMP compliant. Thereafter, Health-Canada conducted regular follow-up inspections of the Apotex facilities and consistently rated those facilities "compliant."

Health-Canada did not require Apotex--did

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require Apotex to require [sic] certain additional information on a monthly basis. Yet, it and the rest of the regulatory agencies worldwide, allowed Apotex to sell its drugs in their countries once Health-Canada deemed Apotex's facilities compliant, notwithstanding the continued Import Alert by FDA. The supervision Health-Canada provided shows its willingness to work with Apotex to address its concerns which, until the Import Alert, had also been FDA's practice and policy.

On October 28, 2009, Mr. Payne, the lead Signet inspector, finished his review of Apotex's response to the Signet 483 and found that Apotex's proposed corrections appeared sufficient for his observations.

Because FDA continued to express a misunderstanding about Apotex's batch rejections, on November 24, 2009, Apotex submitted another detailed analysis of the batch rejection list showing all rejections were well within normal limits. On the same, day the FDA case officer completed her review of Apotex's Protocols and concluded that they adequately

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captured all of FDA's concerns.

By February of 2010, Apotex had made substantial progress on its quality enhancement and assessment projects. It wanted to discuss the results with FDA. Additionally, it wanted to set out a plan for phased re-entry, as is done for domestic companies under a Consent Decree. It requested a face-to-face meeting, which was set for March 31, 2010.

Two weeks before the meeting, Apotex submitted several binders of information detailing Corrective Actions and quality enhancements in reparation for the March 31 meeting. Also, two weeks before the meeting, at an industry cGMP conference, FDA's Mr. Martinez again used Apotex as an example of FDA's new stance on enforcements. He emphasized the swiftness of the action, that the Import Alert was implemented within 10 days of the inspection. He also emphasized the novelty of the action taken against Apotex stating normally FDA gives companies a Warning Letter first, but not Apotex, which he said FDA had never done before.

Two days before the March 31 meeting, without

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any prior notice, FDA issued Apotex a Warning Letter concerning the Signet facility. The Signet Warning Letter came seven months after the Import Alert and eight months after the start of the Signet inspection. The Signet Warning Letter listed four cGMP deviations.

At the March 31 meeting, FDA reiterated its stance that the Import Alert would only be lifted after satisfactory reinspection and not on the basis of documents. FDA also warned Apotex that it must be sure it is ready for re-inspection because FDA will would not rush back if the re-inspection proved unsatisfactory.

On April 17, 2010, Apotex submitted its response to the Signet Warning Letter, which included a detailed description of the Corrective Action Plans and Third-Party Audits that Apotex had implemented.

Two weeks later, Mr. Martinez again referred to the Apotex case. This time, as an example of FDA's taking enforcement action prior to the issuance of a Warning Letter in a letter to Congress.

In May of 2010, Apotex submitted a proposal to resume distribution of products from its

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Indianapolis warehouse that had passed the Apotex Product Quality Assessment, which was a program for evaluating and testing the manufacturing process for Apotex drugs. A month later, FDA denied this request, stating that any decision to resume distribution would be evaluated by the agency during re-inspection.

On June 9, 2010, FDA finally completed its review of Apotex's response to the Etobicoke Warning Letter which had been submitted to FDA way back in July of 2009. It also completed its review of Apotex's response to the Signet Warning Letter. Apotex's new case officer reported to Dr. Rosa that he had reviewed both of Apotex's responses to the Warning Letters and found that they adequately addressed FDA's concern.

At the end of June, Apotex once again requested approval to resume shipping of certain drugs--certain shortage drugs under the oversight of consultants. Apotex detailed again the actions that it had taken and was taking to address FDA's concerns. A month later, FDA denied that request.

By June, Apotex's consultants were prepared

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to certify Apotex as cGMP compliant. FDA refused to allow for third-party certification to permit the sale of certain drugs. In addition, Health-Canada, at that time, had finished an audit of all of Apotex's facilities over a three-month period, June, July and August, and yet again found them cGMP compliant. On August 27, Apotex officially requested FDA to re-inspect the Etobicoke facility. Apotex requested re-inspection of Signet about a month later.

Also in late August, Mr. Martinez, yet again, discussed the Apotex case at an industry conference. He explained to his team that this presentation always receives a lot of publicity in the pharmaceutical press, which would provide a good opportunity to discuss precedent setting or significant regulatory action. He discussed the Apotex case, stating--erroneously--that the Import Alert was issued on August 20, 2009, while the inspection was in progress.

FDA submitted a Priority Inspection Request for Etobicoke on September 22. But by October 13, the inspections for both Etobicoke and Signet still had

not been scheduled.

At that time, Apotex pressed for the scheduling of the inspections and, two days later, FDA communicated the inspection dates to Apotex. The inspections were planned to be commenced on November 29. Originally, FDA had only scheduled one investigator to cover both compasses for three weeks. Then FDA canceled the inspections and delayed it for two more months. Apotex tried to propose different alternatives to get FDA to move up the inspection; all to no avail.

The re-inspection of Signet took place from January 24 to February 11, 2011. The inspection of Etobicoke took place from February 3 to February 10, 2011. 483s were issued, and on March 1, Apotex submitted its response to the Form 483s for the two facilities. On May 6, FDA deemed Etobicoke acceptable. FDA deemed Signet acceptable on June 29. Yet it took FDA at least a month in both cases to actually lift the Import Alert.

Even after the Import Alert was lifted, FDA insisted on another inspection of Etobicoke before it

would begin to approve Apotex's pending ANDAs. This inspection occurred in September, but it still took FDA several more months to approve Apotex's pending ANDAs.

Let me briefly recap what these facts demonstrate. First, in 2009, FDA was attempting to implement a new enforcement policy which included sending a strong message by setting a precedent of major sanctions against at least one alleged offender. FDA repeatedly held up the Apotex Import Alert as proof of its new swift and aggressive approach.

Second, in an effort to comply with FDA's new enforcement approach, FDA rushed to place Apotex on Import Alert without providing Apotex the opportunity to respond to the issues that purportedly formed the bases of the Import Alert.

FDA made the decision to place Apotex on Import Alert the next business day after the Signet inspection without issuing a Warning Letter concerning that facility. FDA provided Apotex no notice of the Import Alert. It provided no opportunity to correct the cGMP issues raised by FDA. In deciding to impose

the Import Alert, FDA did not complete their review of Apotex's responses to either the Etobicoke Warning Letter or the Signet 483.

Third, FDA's decision to impose the Import Alert on Apotex was based on a series of misassumptions. FDA used incomplete information to form its conclusions. FDA did not inform Apotex of any of its growing concerns or give it a chance to address or correct these concerns. FDA did not base its conclusion on the actual findings of the Etobicoke inspection.

Finally, by placing Apotex on Import Alert, FDA unduly exacerbated the already grave impact the Measure had by delaying its--in delaying analysis of Apotex's submission and in delaying the re-inspection of the facility.

Moreover, once FDA actually reviewed all of the material that Apotex submitted in response to the Etobicoke and Signet Warning Letters and 483s, it found Apotex's responses to be adequate and appropriate. This shows that had FDA followed its normal procedure, the one that it applied to Apotex's

comparators, there would have been no reason for an Import Alert.

The facts concerning the treatment of Apotex's comparators will be addressed in the upcoming presentation on National Treatment and Most-Favored-Nation Treatment. So I will conclude now and, in conclusion, thank you for your time and attention.

I'm happy to any answer questions that you might have.

PRESIDENT VEEDER: Thank you. Do you have any questions?

ARBITRATOR CROOK: Thank you, Mr. Hay.

I wonder if you are able to or if at some point it can be clarified for us where these various people stood in the FDA bureaucracy. Where was Ms. Woodcock? Where was Mr. Martinez? What was the relationship hierarchically, if any, between Ms. Woodcock and Dr. Rosa?

Can you tell us how these people fit together?

MR. LEGUM: I'll provide the exhibit number

in a moment, but there is a contemporaneous organization chart for the Division of Manufacturing Quality--Manufacturing and Product Quality at FDA that will be helpful. So once we find that, perhaps we can go through it.

ARBITRATOR CROOK: And CDER is a subpart of that?

MR. LEGUM: So CDER is the Center for Drug Evaluation Research.

ARBITRATOR CROOK: Let's not improvise. If there's an exhibit, that would be great.

MR. LEGUM: Or, if you have Exhibit C-489 handy, we can do it now.

ARBITRATOR CROOK: That's all right.

MR. LEGUM: It's your pleasure.

PRESIDENT VEEDER: C-489.

Thank you very much. We have no further questions at this stage, but no doubt later we may do.

It's now 12:00. What happens next?

MR. LEGUM: Next on the agenda is to turn to jurisdiction. We'll require a short interval to, I guess, put the feed back on and also to switch the

operators of the slide.

PRESIDENT VEEDER: How long do you need?

MR. LEGUM: Five minutes.

PRESIDENT VEEDER: Let's take five minutes. Thank you.

(Brief recess.)

PRESIDENT VEEDER: Let's resume. We'll just ask our Secretary first to confirm the status of the feed.

SECRETARY TAYLOR: Upon the Claimants' notification, the feed has now been resumed to the public hearing room.

PRESIDENT VEEDER: Thank you.

NONCONFIDENTIAL PORTION

PRESIDENT VEEDER: Claimants have the floor.

MR. LEGUM: Thank you, Mr. President.

Members of the Tribunal, it is my honor to begin Apotex's presentation on the jurisdiction of this Tribunal to hear the claims submitted in this arbitration.

In this presentation, Apotex will first recall the many issues relating to jurisdiction that are undisputed on this record. We will then address the United States' Objection to Jurisdiction based on the phrase "relating to" in the NAFTA Investment Chapter's Scope and Application Provision.

We will then address the objection that Marketing Authorizations for pharmaceutical products are not investments within the meaning of the Article 1139.

The precise order of our presentation and the team members who will address the Tribunal are set out in the printed agenda before you.

For the reasons set out in Apotex's pleadings and those that will be recalled today, Apotex

respectfully submits that the Tribunal should dismiss the U.S. objections to jurisdiction.

So as indicated a moment ago, all of the elements of jurisdiction under the NAFTA save two are undisputed in this case. The principal requirements for jurisdiction are set out in Articles 1116(1) and 1117(1) of the NAFTA. There is no dispute that Apotex Holdings and Apotex-Canada are Canadian enterprises. There is no dispute that Apotex Holdings is an investor of a Party as concerns Apotex-U.S. The Parties agree that Apotex-U.S. is an enterprise and an investment of Apotex Holdings.

The United States, the Respondent here, is of course another Party within the meaning of Articles 1116 and 117.

There is also no dispute that Apotex Holdings indirectly controls Apotex-U.S., and that Apotex-Canada directly owns the Marketing Authorizations and Apotex Holdings indirectly controls the Marketing Authorizations.

Now, the Parties further agree that the temporal requirements of the NAFTA have been made and

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12:09:40 the formal elements satisfied. The arbitration was commenced within three years of the adoption of the Import Alert, in August 2009. The satisfaction of the formal elements of timely notice of intent, consent to arbitration and waiver, under Article 1120 is not contested.

The dispute on jurisdiction here focuses on two elements that are mentioned in the scope and application provision of the NAFTA's "Investment" chapter. According to Article 1101(1), the Investment chapter applies to Measures adopted or maintained by a Party relating to investors of another Party and investments of investors of another Party in the territory of that Party.

The key elements are a "Measure" "adopted by a Party" that "relate to investors or investments of another Party."

Apotex maintains that all of these key components are present here. The U.S. does not dispute Apotex's contention with respect to three of those components: That the Import Alert is a Measure, that it was adopted and maintained by a Party, and

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12:10:55 that Apotex is--Apotex Holdings is an investor of another Party with an investment in U.S. territory in the form of Apotex-U.S.

Two main issues remain in dispute: Whether the Import Alert related to the investments at issue, and, therefore, to Apotex; and whether Apotex's Marketing Authorizations constitute an investment under Chapter 11.

I'll begin our discussion of these two disputed issues by addressing "relating to."

As noted, Article 1101 provides that the Investment chapter applies to Measures relating to the investor or its investment. As held by the Methanex Tribunal, the terms "relating to" in Article 1101(1) imply a legally significant connection between the Measure and the investor or the investment. The Parties agree here that a legally significant connection is required.

The U.S. argues, however, that the requisite legally significant connection does not exist between the Import Alert on the one hand and Apotex Holdings as an investor in Apotex-U.S. as its investment on the

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12:12:22 other hand.

The U.S. does not develop in its objections what kind of a connection is required here to be legally significant. The U.S. initially appeared to suggest in its Counter-Memorial that for a legally significant connection to be present, the Measure must either apply to the investment, constitute a legal impediment to its business, or be addressed to the investment. The.

U.S. has expressly disavowed those positions since without, however, offering any alternative approach. The U.S. objections to jurisdiction, thus, leave Apotex with no statement of the case that it is to meet that is based on principles. Instead, it is based on a disparate and unconnected series of factual arguments.

In my presentation this afternoon, I will demonstrate the correct content of "legally significant connection" as required by Article 1101(1), I will demonstrate that correct content based on an analysis under Article 31 of the Vienna Convention on the Law of Treaties. We will

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12:13:45 show that the connection required by the NAFTA is present here.

I will then discuss--or, actually, Ms. Dufêtre will then discuss, after lunch, the U.S. submission on this issue which, as I noted, is not based on principles but, rather, on an ever-changing succession of disjointed factual assertions. We will demonstrate that the record does not support the United States.

Under Article 31 of the Vienna Convention on the Law of Treaties: "A Treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the Treaty in their context and in the light of its object and purpose."

The Ordinary meaning of the terms "relating to" was addressed by the Methanex Tribunal. The Tribunal found that to require, as I've noted, a legally significant connection between Measure and investor or investment.

What makes a connection legally significant is not answered by the ordinary meaning of "relating to." One must consider other elements under

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12:15:00 Article 31 of the Vienna Convention for guidance on this point.

So turning to the context of those terms, the context of Article 1101(1) includes, among other things, the other provisions of Chapter 11 of the NAFTA, including those that immediately follow Article 1101(1) and set out the substantive obligations of the NAFTA Parties. Each substantive provision specifies the connection between "Measure" and "investment" required for there to be a breach.

So Article 1102 requires a NAFTA Party to accord treatment to a covered investor that is no less favorable than that accorded to national investors with respect to their investments.

Treatment accorded is necessarily through a Measure adopted or maintained by the Party, whether the Measure concerns the covered investor or the national one.

After Article 1102 sets out the connection that is required between the Measure and the investor or the investment. If the Measure accords treatment in like circumstances that is less favorable, the

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12:16:30 NAFTA Party will be in breach of Article 1102.

Article 1103 requires the same type of connection, but this time with a third-country investor--or third-country-owned investment as the comparator.

Article 1105(1) requires a NAFTA Party to accord to a covered investment treatment in accordance with international law, including fair and equitable treatment and full protection and security. Again, treatment by a Party is necessarily accorded through a Measure or, in the case of full protection and security, by the absence of a Measure that ought to have been taken.

The provision sets out the connection that is required between the Measure and the investment. If the Measure fails to accord treatment in accordance with international law to the investment, the NAFTA Party will be in breach of Article 1105(1).

Breach of an international obligation in and of itself is legally significant as it gives rise to State responsibility and such breach stems from the Measure. It, therefore, follows that the connection

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12:17:54 between "Measure" and "investment" or "investor" set out in the relevant substantive articles is necessarily legally significant.

NAFTA jurisprudence supports this reading. For instance, the Tribunal in the Methanex case reasoned--and I'll quote--"An affirmative finding of the requisite relation under NAFTA Article 1101...does not necessarily establish that there has been a corresponding violation of NAFTA Article 1102...but an affirmative finding under NAFTA Article 1102...could conceivably provide evidence relevant to a determination as to whether the 'relation' required by NAFTA Article 1101 exists in this case."

Now, it is correct, as the United States points out, that the Methanex Tribunal found on the record in that case no substantive violation that could have aided in the Tribunal's analysis under Article 1101(1). Methanex, however, was an extreme case in which the Measure not only did not address the Claimant, but did not even address the Claimant's industry or any product the Claimant sold. This case does not remotely resemble Methanex. The Tribunal's

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12:19:20 approach in that case to considering the record on the substantive provisions in determining the case under Article 1101, however, supports the reading that Apotex advances here.

Now, the objective and purpose of the NAFTA further reinforces the submission that Apotex makes.

Article 102(1) of the NAFTA says out--and I quote--"The objectives of this Agreement as elaborated more specifically through its principles and rules, including National Treatment, Most-Favored-Nation Treatment and transparency are to...increase substantially investment opportunities in the territories of the Parties."

Now, Article 1101(1) must be interpreted in the light of that object, the object of increasing substantially investment opportunities in the territories of the Parties.

Article 1101 has been described by the Methanex Tribunal as a Gateway to Chapter 11. The substantive provisions of that chapter set out the specific principles and rules--including National Treatment, Most-Favored-Nation Treatment, and

Transparency--that the NAFTA Parties deemed necessary to achieve their objective of substantially increasing investment opportunities.

For that objective to be met, the Gateway of Article 1101 cannot be more narrow than the specific principles and rules elaborated by the NAFTA Parties in the Investment chapter. A Gateway set more narrowly than the principles and rules will restrict, not increase, investment opportunities in the NAFTA States. It will prevent the objectives of the Treaty, as elaborated through its specific principles and rules, to be realized.

By contrast, understanding that the connection between "Measure" and "investor" or "investment" required by the specific rules and principles to be legally significant ensures that Article 1101's Gateway will meet the objectives of the Treaty.

Accordingly, the text, context, and object and purpose of the NAFTA all support Apotex's position that the connection between "Measure" and "investment" contemplated by Articles 1102, 1103, and 1105 is

legally significant for purposes of Articles 1101(1).

As Apotex demonstrated in its pleadings and as we will recall in the later presentation of our Case-in-Chief, the record here amply establishes that the United States breached Articles 1102, 1103, and 1105 by adopting and maintaining the Import Alert. The connection between "Measure" and "investor" or "investment" contemplated by those Articles is present on this record. And the Measure does, indeed, relate to Apotex and its investments.

So that concludes the first part of our presentation.

It's 12:25 p.m., and we are at the Tribunal's disposal should it wish to break for lunch at this time.

PRESIDENT VEEDER: We started early this morning, why don't we break now and pretend it's 12:30 instead of 12:25 and we'll come back at 2:00 to hear the rest of your submissions.

Thank you very much.

(Whereupon, at 12:23 p.m., the hearing was adjourned until 2:00 p.m., the same day.)

AFTERNOON SESSION

PRESIDENT VEEDER: Let's resume. We're in open session, and the Claimants have the floor.

MS. DUFÊTRE: Thank you, Mr. President.

Mr. President, Members of the Tribunal, it is a great pleasure and honor to be appearing in front of this Tribunal today.

We are addressing the jurisdictional objection on "relating to" as we started this morning, and in this part of our presentation, we will show that the record belies all of the assertions made by the United States in support of this objection on "relating to," namely that the Import Alert does not relate to Apotex-U.S. or Apotex Holdings.

The U.S. has offered a succession of factual assertions, and Apotex demonstrated that each has no support in the record. Following Apotex showing, the U.S. tactics has been to ignore Apotex arguments.

In its Rejoinder on Merits and Counter-Memorial on Jurisdiction, the U.S. did not respond to detailed arguments and evidence presented by Apotex. Instead, the U.S. has continued to make a

series of incorrect allegations.

First, the U.S. argued that the Import Alert was too remote from Apotex-U.S.

Second, the U.S. argued that the Import Alert was not addressed or applied to the Apotex-U.S., but instead to FDA field offices.

Three, the U.S. questioned whether the Import Alert was published on August 28 or September 30, 2009, but this issue is not relevant to the argument on "relating to."

Four, the U.S. rehashed its arguments that there was no special relationship between Apotex-Canada and Apotex-U.S.

And fifth, the U.S. argued that Apotex-Canada sent products to three U.S. consignees other than Apotex-U.S. for commercial sales in the United States.

I will address each of the U.S. mistaken allegations, and I will conclude with a quick word on the arguments that the U.S. now seems to have dropped.

So the first mistaken allegation: The U.S. alleged, among other things, that the Import Alert did not relate to Apotex-U.S. because, according to the

14:05:43 U.S., the link between the Measure and investment was too remote. Here the U.S. relies on a commentary to Article 31 of the ILC Draft Articles on State responsibility.

Article 31 is the provision that states that a state must make full reparation for an injury caused by a wrongful act, an internationally wrongful act.

The commentary relied upon by the U.S. states the timeworn proposition that indirect or remote damages may not be awarded. This debate will only become relevant, if at all, during the damages phase of this arbitration, but it sheds no light on the "relating to" or the requirements set out on Article 1101(1) of the NAFTA.

Throughout its pleadings, the U.S. had favored rhetoric over substance. As part of this strategy, the U.S. simply does not address the evidence that it doesn't like or that doesn't fit its case.

I will give you a couple of examples. The first example has to--deals with the labels for Apotex drugs.

14:07:04 The FDA was aware that Apotex-U.S. was the distributor of record for all Apotex drug products sold on the U.S. market. Every time that Apotex wants to distribute a new drug on the U.S. market, it must first obtain a Marketing Authorization.

Before granting such authorization, FDA will review the label and the patient leaflet that will accompany any given product. These labels show--and you have an example on the screen for a particular label. These labels all clearly show that Apotex-U.S. was the distributor for the particular drug.

Again, we've made that point clearly in our pleadings, but the U.S. response in its Rejoinder was simply silence.

Apotex witnesses have also explained that Apotex-U.S. was set up specifically to distribute Apotex products in the United States. U.S. courts have held that Apotex-U.S. is, "the distribution arm of Apotex in the United States." And I refer you to CLA-536.

The U.S. has ignored this holding and the fact that Apotex-U.S. clearly is the distribution arm

14:08:31 of Apotex in the United States.

Here is another fact that the U.S. fails to address. When Apotex products were detained as a result of the Import Alert, the FDA's notices of actions were specifically addressed to Apotex-U.S. as the consignee of the detained products. And we have now the relevant exhibits on the screen.

The fact that the FDA's notices of action were addressed to Apotex-U.S. is in accordance with U.S. law, U.S. regulations, as well as FDA guidance documents.

These provisions provide that both the owner and the consignee of the articles offered for import in the United States should receive a notice of detention and hearing. And just as a reminder, we can now see the relevant provision on the screen. This is undisputed.

I now come to my second point. Faced with this clear record, the U.S. simply offers no response. In its Rejoinder, the U.S., instead, argues that the Import Alert was not addressed or applied to Apotex-U.S., but, rather, to FDA field offices. But

14:10:08 here, again, the U.S. does not respond to Apotex's arguments that the Import Alert necessarily apply to Apotex-U.S. since the Import Alert interrupted the transactions on which Apotex-U.S. depended for 80 percent of its sales.

The Import Alert decimated Apotex-U.S. sales. As a result, Apotex-U.S. dropped from the 6th to the 26th position on the generic drug market on the United States between January 2009 and 2012.

Clearly, in the circumstances, the Import Alert was a legal impediment on Apotex's business.

The U.S. cannot rebut this showing, and the U.S. fails to distinguish Cargill, the case that sets out the legal impediment standard. So, once again, the U.S. simply ignores the evidence and the relevant jurisprudence.

I now turn to my third point. In order to distract the Tribunal's attention from the vacuum in its case, the U.S. attacks a straw man.

The U.S. questions whether the Import Alert was published on the 28th of August or on the 30th of September 2009.

If we look at the Import Alert itself, the answer is clear. On the document, it is stated that the Import Alert was published on September 30, 2009.

Apotex became aware of the Import Alert before that date, as the record also shows, but there is no evidence of the Import Alert being published prior to that date. And, in any event, what does the publication date have to do with the "relating to" issue?

I move to my fourth point. The U.S. does not address the detailed showing made in the Reply that there were no contradiction between Apotex's statements before this Tribunal and prior statements made before U.S. courts.

Here, the U.S. simply rehashes its arguments that there is no special relationship between Apotex-Canada and Apotex-U.S., but the U.S. fails to respond to Apotex simply because it has no response. Tellingly, the U.S. chose not to call any Apotex's witnesses who, according to the U.S., gave the contradictory statements.

There is no contradiction in the testimony

given by Apotex employees. We responded point by point to the U.S. allegations concerning the so-called contradictions in those statements. I will not repeat that here, and I will simply refer the Tribunal to Paragraphs 175 to 204 of our Reply.

I also note that the U.S. fails to explain why the relationship between Apotex-Canada and Apotex-U.S. has any bearing on the "relating to" question.

Apotex emphasized that the special relationship between the two companies as part of its arguments on Article 1139(h). It has nothing to do with the jurisdictional objection on 1101(1). Again, when we made this response, the U.S. did not offer any counterargument.

Moving on to my fifth observation. In our Reply, we explained at length why Apotex-U.S. was uniquely affected by the Import Alert, and this is so because Apotex-U.S. is the sole importer for commercial sale of products manufactured by Apotex-Canada for the sale in the United States.

Again, the U.S. offers no response to the

Apotex's explanations and the supporting evidence. Instead, the U.S. argues that Apotex-Canada sent products to other U.S. consignees for commercial sales in the United States.

However, Mr. Fahner explained that Apotex made three drop shipments on behalf of Apotex-U.S. to its customers. The three drop shipments were made by Apotex-Canada on behalf of Apotex-U.S.

Apotex-U.S. paid Apotex-Canada for the products, and it was Apotex-U.S. who sold the products to the U.S. distributors. The U.S. did not take Mr. Fahner's explanations into consideration. The U.S. also ignores the evidence supporting Mr. Fahner's explanations.

What you have on the screen now is one of--one commercial invoice for one of the three drop shipments. I note that the version on the screen has redactions, but the evidence in the record does not, for the reasons that Mr. Legum explained this morning.

So, if we look at this exhibit, there are three key points: The product in question was sold by Apotex-U.S. to the final customer; the product was

distributed by Apotex-U.S.; and the invoice required payment to be remitted to Apotex-U.S.

Therefore, the record does not support the U.S. argument that other U.S. companies besides Apotex-U.S. were equally affected by the Import Alert. There is no supporting evidence for these U.S. assertions.

So if I try to sum up, the U.S. does not address the case put forward by Apotex on the issue of "relating to." Instead, the U.S. ignores the vast majority of Apotex's argument and supporting evidence, which clearly show that the Import Alert related to Apotex-U.S.

I will now make a final observation and say--make two remarks about arguments that the U.S. now seems to have dropped.

The Tribunal may recall that in its Counter-Memorial, the U.S. relied on a listing of customers from whom Apotex recalled products in 2009. The U.S. incorrectly assumed that these customers were customers of Apotex-Canada, but this is not the case. All of the customers on this list are customers of

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14:17:33 Apotex-U.S., not Apotex-Canada, and this was explained by Mr. Fahner in his Second Witness Statement. The U.S. has now dropped this argument.

The U.S. also seems to have dropped the argument that it initially tried to make on the basis of FDA spreadsheets based on FDA import database. And here I refer to Exhibits R-115, R-118, and R-119.

The U.S. argued that this spreadsheet showed that there were other companies in the United States besides Apotex-U.S. who were equal affected by the Import Alert. However, the U.S. misunderstood its own evidence. In fact, the spreadsheets show that Apotex-U.S. was uniquely affect by the Import Alert.

In its Rejoinder, the U.S. does not respond to the showing made by Apotex's Reply with respect to the three spreadsheets. The U.S. does not dispute that most entries on the spreadsheets recorded shipments made by third parties completely unrelated to Apotex.

The U.S. also does not dispute that the few shipments that were actually made by Apotex-Canada--and here we're talking about 11

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14:19:09 shipments out of 322 for the relevant time period. The U.S. does not dispute that these few shipments to consignees in the United States other than Apotex-U.S. were not shipments for commercial sale.

And, finally, the U.S. does not dispute that 99 percent of the shipments to consignees other than Apotex-U.S. were allowed to proceed in the United States while all shipments from Apotex-Canada to Apotex-U.S. were detained during or could not enter the U.S. during the Import Alert.

In conclusion, the record clearly shows that the Import Alert related to Apotex-U.S. The U.S. has offered no convincing evidence to the contrary. In fact, faced with the inter-contradiction in its claim, the U.S. has simply declined to address most of Apotex's arguments and supporting evidence. However, Apotex case and evidence extend.

I will now turn the floor to Mr. Legum, who will now address two new arguments that were raised in the U.S. Rejoinder on "relating to."

MR. LEGUM: Thank you. As Ms. Dufêtre just mentioned, in this part of our presentation, I will

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14:20:42 concentrate on two arguments raised for the first time in the Rejoinder, to wit: that the sales of Apotex products at issue occurred in Canada, not in the U.S.; and that the Measure preventing the importation of Apotex products was, in fact, not the Import Alert, but a trinity of different Measures. I will address each of these arguments in turn.

In its Rejoinder, the U.S. accused Apotex of withholding crucial facts in its exclusive control concerning the location of Apotex's drug sales. And it asserted that that location is a central element of Apotex's claims.

Well, first, Apotex has produced the only documentation that exists of sales between Apotex-Canada and Apotex-U.S. Specifically, Apotex produced the commercial invoices that document the sales between Apotex-Canada and Apotex-U.S. These invoices show that Apotex-Canada was the shipper, Apotex-U.S. was the buyer, and that the drugs were shipped from Apotex-Canada to Apotex-U.S.'s facility in Indianapolis, Indiana.

Now, what you see on this screen is just one

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14:22:07 example of a commercial invoice for the shipments at issue. Apotex has submitted other commercial invoices as exhibits in its written pleadings, and these exhibits are listed in Footnote 5 of Apotex's Rejoinder on Jurisdiction.

Apotex also produced the FDA Notices of Action reflecting the U.S.'s contemporaneous understanding of the transactions. These show Apotex-Canada in Ontario as the importer of record and Apotex-U.S. in Florida as the consignee of the shipments.

The pertinent facts concerning these transactions, as Apotex understands them, are reflected in these documents. Notably, the U.S. does not identify what other crucial facts it believes are lacking. In any event, it is unclear from the U.S. submission why the location of sales is a central element of Apotex's claims.

Articles 1102, 1103, and 1105, read with Article 1101(1), require a showing as to the location of Apotex's investments. Apotex has made that showing.

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14:23:32 The location of sales is not an element of Apotex's claims. If the U.S. believes that the location of the sales is pertinent to the U.S.'s defense, the U.S. had a full opportunity to obtain any relevant documents on that subject from Apotex during the disclosure phase of this arbitration.

The U.S. chose not to do so. The U.S. did not request any document on this topic from Apotex. If there is a Lacuna in the record, it is not one in Apotex's case.

Moreover, the location of sales in a cross-border transactions is not a fact. It is a complex legal conclusion. The conclusion may vary depending on the context in which the relevant question is asked.

For example, the lex loci applicable to the validity of a contract may be different from that applicable for purposes of determining whether the buyer or the seller bears the risk of loss of the goods.

The U.S. is silent what it has in mind by the location of sales, though it points in its

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14:24:42 argument--it seems to attach significance to where legal title passes.

Most important, the U.S. does not articulate why or how any of this is relevant to the connection between Apotex-U.S. and the Import Alert. If title passed in Canada, as the U.S. suggests, that would simply imply that Apotex-U.S. was the owner of some of the products that were the subject of the Import Alert.

It is far from clear, however, why this would weaken the connection between that Measure and Apotex-U.S. The U.S. does not explain why the Import Alert would any less relate to an owner prevented from receiving its property than it relates to a perspective owner; in other words, a purchaser that has not yet acquired title.

The key point here, for purposes of Article 1101(1), remains undisputed. The Import Alert cut Apotex off from 80 percent of the supply that it depended on for its business. The Import Alert decimated that business while competing investments owned by U.S. and third-country nationals were able,

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14:26:02 in like circumstances, to sell product without impediment. The Import Alert related to Apotex-U.S.

I come now to the second of the U.S. arguments, one advances for the first time after the filing of the Counter-Memorial.

The U.S. seeks to deconstruct the Measure at issue here into a trinity. The U.S. argues that the real Measure that prevented Apotex-U.S. from receiving 80 percent of its supply was FDA's findings of cGMP noncompliance, not the Import Alert.

It argues that the Second Measure in the trinity, the Import Alert, was mere guidance that did not cause Apotex-U.S. any harm.

The Third Measure in the U.S. trinity is the detention of products by FDA officials at the border, which the U.S. asserts was based on the cGMP findings and not the Import Alert.

This objection to jurisdiction based on the trinity of Measures fails for two reasons. First, it comes too late; and second, it is not supported by the record.

The objection comes too late because it was

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14:27:17 first raised after the filing of the U.S. Counter-Memorial, Article 45(2) of the ICSID Additional Facility Arbitration Rules does not permit new objections to jurisdiction after that date except under circumstances not present here. The objection is inadmissible.

The objection, in any event, is without merit. It finds no support in evidence. The record does not sustain the U.S. effort to deconstruct the Import Alert into three Measures; instead, it shows that it was the Import Alert that caused FDA to refuse admission of Apotex's products.

To provide a few examples: First, the document that the U.S. references as the real measure for Signet was the Warning Letter for that facility that was issued in March 2010.

Now, if that was the real measure, why is it and on what basis was it that the U.S. border officials began refusing admission of Signet products into the U.S. almost seven months earlier in, August 2009? If the real measure for Signet was a March 2010 Warning Letter, why did border officials

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14:28:42 start turning back trucks in August 2009? The U.S. does not explain this mystery.

The document that the U.S. references as the real measure for Etobicoke was the Etobicoke Warning Letter that was issued in June 2009.

Now, if that was the real measure, why is it that FDA did not begin refusing admission of Etobicoke products until two months later, at the end of August 2009, at the time the Import Alert was adopted? Again, the record does not support the U.S. position.

FDA's contemporaneous correspondence, both internally and with Apotex confirms, that it was the Import Alert that prevented Apotex from importing its products into the U.S.

On the screen here, you have an internal FDA e-mail chain in which--could we go back to the beginning?

Okay. So you have a series of internal FDA e-mail chain here. The first one, which you see on the screen now, is the exchange of Deb Autor, with her staff at the Office of Compliance at CDER, where she asks, "Can we do an Import Alert sooner rather than

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14:30:10 later?" And the Director of CDER, Janet Woodcock, "Obviously, this firm should not be shipping drugs to the U.S."

So CDER, in its internal discussions, is referring to the Import Alert as what would stop a firm from shipping drugs to the U.S. It is not referring to some other measure.

This chain is consistent with other e-mail chains, which you're now seeing very quickly on the screen.

All right. So my point here is that the contemporaneous correspondence between FDA and Apotex and the internal correspondence within FDA is consistent with the Import Alert being the Measure that stopped the importation of the products and not any of the other two Measures.

Moreover, the comparators in this case, which FDA found to be similarly cGMP noncompliant and which received similar warning letters, were not prevented from distributing their products in the U.S. The only difference between the comparators and Apotex was that the comparators were not subjected to an Import Alert

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14:31:45 or an equivalent enforcement action while Apotex was.

The record thus shows that the relevant actors at the relevant time thought that the relevant Measure was the Import Alert. The sequence of events shows that it was the Import Alert that cut off Apotex's supplies and the absence of an Import Alert, or Measure of an equivalent effect, allowed competing investments to continue and receive and sell their products on the U.S. market.

The U.S.'s new theory regarding the trinity of measures is an armchair analysis that is divorced from the record. It is without merit.

Now, I'd like to turn to the second half of our presentation on jurisdiction, which is that the Apotex-Canada's ANDAs are covered investments.

I begin by noting that Apotex's submission is that these Marketing Authorizations constitute investments because they are, first, intangible property within the meaning of the Article 1139(g); and they constitute interests arising from the commitment of capital or other resources under Article 1139(h) of the NAFTA.

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14:33:09 Now, it would be sufficient for Apotex's Marketing Authorizations to satisfy the test of either Article 1139(g) or Article 1139(h). In this case, Apotex's submission is that both are satisfied.

At the outset, and before discussing subparagraphs (g) and (h) of Article 1139, I'd like to address the argument advanced by the U.S. based on the recent decisions rendered by different Tribunals in two unrelated cases between Apotex-Canada and the U.S.

Apotex Holdings was not a party to that case. The U.S. argues that these cases support the U.S.'s position that Marketing Authorizations are not investments. The two cases pertain to two applications for approval of drugs for marketing in the U.S.

The drugs concerned were sertraline and pravastatin. And I would simply note as an aside that Ms. McLeod, in her presentation this morning, suggested that Apotex did not lack finally approved ANDAs for these products at the time.

In fact, the only issue before the Tribunal--the dispute in that case, that is--concerned

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two applications for approval. They did not--that case did not address any finally approved ANDAs. And I'd refer to the Tribunal to Paragraphs 15 and 16 in the Apotex I and II Award for that proposition.

The U.S. argues that the Tribunal's decision in Apotex I and II constitutes res judicata on certain issues in this proceeding. Specifically, the U.S. argues that Apotex I and II recently confirmed that Apotex's Marketing Authorizations are neither property, within the meaning of the Article 1139(h), nor interests arising from the commitment of capital or other resources, within the meaning of Article 1139(h).

Did I say (h) before? It should be(g) and (h), for the clarity of the record.

The U.S.'s res judicata argument fails on several grounds.

First, the Award in the Apotex I and II case is binding between Apotex-Canada and the United States, but only in respect of that case. The disputing parts here agree that Article 1131(1) of the NAFTA specifies the applicable law for this Tribunal's

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assessment of the binding effect of a prior NAFTA Award.

That article provides that "A Tribunal established under this section shall decide the issues in dispute in accordance with this Agreement"--that is, the NAFTA--"and applicable rules of international law."

The binding effect of a NAFTA Award must be determined under the NAFTA and international law. The NAFTA specifically addresses the binding effect of Awards under the Investment chapter in Article 1136(1). And you see the text of that provision on the screen. That provision provides "An Award made by a Tribunal shall have no binding force except between the disputing Parties and in respect of the particular case."

This text corresponds to the general approach to res judicata in public international law and to Article 59 of the Statute of the International Court of Justice.

It is well established that for the principle of res judicata to apply under international law,

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three conditions must be satisfied. These must be--and this is taken from an article by Professor Vaughan Lowe that the United States relies upon--identity of the Parties, identity of the cause or the issue, and identity of the object or subject matter.

This triple identity test clearly is not satisfied in this case. Here there is no identity of the Parties. One of the Parties is different from the Parties in Apotex I and II. There is no identity of cause. And there is no identity of object. The U.S.'s res judicata argument fails as a matter of international law.

Now, second, apart from Apotex I and II not constituting res judicata for issues arising in this case, the U.S. argument fails also because it is premised on a concept that is not supported by international law. Specifically, as the U.S. acknowledge in its Reply--excuse me--its Rejoinder, the argument hinges on the proposition that an international law, and "res judicata includes the principle of issue estoppel." This is the U.S. rejoinder at Paragraph 99.

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That proposition, however, is incorrect. As Professor Lowe states, "There does not appear to be any explicit decision of a prominent international Tribunal on the question of issue estoppel."

The U.S. cites only two authorities in support of its argument on issue estoppel. Neither one supports its case.

The first is the Company General of the Orinoco case. In this case, from the beginning of the last century, the umpire was not applying international law, but, instead, the principles of absolute equity. And the reference to the Protocol that set out the jurisdiction of the umpire is found in the Rejoinder on Jurisdiction of Apotex.

In justifying his equitable decision, the umpire made a passing reference to a U.S. Supreme Court decision applying the common law notion of issue estoppel. It speaks volumes that the U.S. must resort to a reference of this nature, a reference to a justification of a decision not under international law, but under absolute equity, to justify its position on issue estoppel.

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14:40:18 The second of the authorities mentioned by the U.S. is an International Law Association report. That source is of no avail here for two reasons.

First, the ILA Report sets forth proposals for principles of res judicata in International Commercial Arbitration. It expressly declined to address investment treaty arbitrations. The Report noted--the language is on the screen--"that the recommendations do not address issues related to investment arbitration because they pertain more to public international law than to International Commercial Arbitration or at least to the hybrid legal order of BIT arbitrations."

Accordingly, they have only some direct--indirect relevance for BIT arbitrations. Thus, these ILA Report recommends do not address the rules of public international law applicable here.

In addition, the ILA Report sets out recommendations that reflect the principles that a certain number of scholars espouse on how applicable law might progressively be developed. As such, they are de lege ferenda. They do not show what the law

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14:41:38 is; they show what some people believe it should be.

Accordingly, neither Company General of the Orinoco nor the ILA Report supports the U.S. argument in this case, and the U.S. cites to no other authority.

Neither NAFTA nor international law, more generally, supports the proposition that Apotex I and II precludes this Tribunal from addressing any of the issues before it, including the issue of whether Apotex has Marketing Authorizations. At issue in these proceedings constitute investment under Article 1139(g) and (h).

As I mentioned before, under Article 1136(1) of the NAFTA, Apotex I and II is binding only in respect of that particular case. It is not binding in respect of this one.

The NAFTA Parties could have, in drafting that provision of the Treaty, adopted a different rule on the preclusive effect of Arbitral Awards, even a rule that includes the U.S. current proposal of issue estoppel.

They did not. This is likely because the

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14:42:52 sword in question cuts both ways, and the NAFTA Parties are more likely to be confronted with repeat issues than anyone.

Take the high-fructose corn syrup cases against Mexico, for example. Mexico was able to continue arguing that the Measure in those cases did not breach the NAFTA, even after a Tribunal finally decided that the Measure was a breach. Under at least the U.S. national law variation of issue estoppel, this would not have been possible.

Third, even if the U.S. was correct in its submission about the general applicability of issue estoppel in international law, which the U.S. is not, the ultimate result in this case would still be the same. This Tribunal is not precluded from deciding any of the issues addressed by Apotex I and II.

The U.S. restatement of the law second on judgments acknowledges that for issue estoppel to apply, the issue of law or fact must have been actually litigated and determined by a valid and final judgment and that determination must be essential to the judgment.

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14:44:16 The status of the Marketing Authorizations at issue in this proceedings was not decided by the Apotex I and II Tribunal. The issue before that Tribunal was whether applications for Marketing Authorizations could constitute an investment under the NAFTA.

That Tribunal was not called upon to decide, and it did not decide, the issues that arise in this case, whether Apotex's finally approved Marketing Authorizations--in other words, finally approved ANDAs--were investments.

The status of Apotex's Marketing Authorizations was not actually litigated and determined. Any comments made by the Apotex I and II Tribunal concerning the status of finally approved Marketing Authorizations could not be essential to the judgment in that case.

Put differently, Apotex I and II considered and decided the issue of whether applications for approval of two products could be considered property under Article 1139(g).

That Tribunal made its decision concerning

those two applications in the context of decisions by the Courts and the FDA concerning those applications. That Tribunal did not address or decide the issue of whether finally approved Marketing Authorizations concerning scores of other products can be considered investments under Article 1139(g) and 1139(h) in the context of an Import Alert that prevented marketing of the products that were authorized.

Accordingly, although the Apotex I and II decision is, indeed, binding in respect of that particular, as Article 1136(1) of the NAFTA provides, it does not prevent this Tribunal from addressing the issues before it.

Now, unless there are any questions from the Tribunal, I will turn the floor over to Ms. Dufêtre to address the 1139(g).

PRESIDENT VEEDER: We have some questions on the scope of your res judicata argument.

If we can start with NAFTA Article 1136 on the finality of an award. You pointed that to us at Slide 41, CLA-1, and you pointed to the words "an Award made by a Tribunal shall have no binding force

except between the disputing Parties," and you make that distinction between Apotex Inc. and Apotex Holdings Inc. and in respect to the particular case.

Now, if you just take those words, you say that would not prevent Apotex Inc. starting a new arbitration against United States on the very same issues that were determined by the Award to which you referred. Could they start again?

MR. LEGUM: Another case concerning those two products? Absolutely not.

PRESIDENT VEEDER: Why not, given Article 1136?

MR. LEGUM: Because that particular case concerned those two products, and so--

PRESIDENT VEEDER: The case would cover the dispute? It wouldn't just be the arbitration case?

MR. LEGUM: Correct.

PRESIDENT VEEDER: Okay. Now, if we go a little bit further, if the Legal Advisers to Apotex Inc., having lost on this Award on jurisdiction admissibility, advised Apotex to restart their particular litigation--that is, in regard to

applications for approval for these two products--could proceedings be initiated by Apotex Holdings Inc., bypassing any problem on res judicata?

MR. LEGUM: I'd like to reflect upon that question and come back to you with a more considered response, but my initial reaction is that that would not be possible because of, among other things, the waiver that's required under Article 11--

PRESIDENT VEEDER: I accept all that. Just on the problem, would res judicata be an immediate answer to that new arbitration if brought by Apotex Holdings Inc. or nonparty, different from Apotex Inc.?

Take your time to think about it, but there is some other material, and I'm going to ask my colleague, Mr. Rowley, to refer to it briefly.

MR. LEGUM: Before you do, could I just--is there anything that can be done on the sun? Because we're kind of melting on this side of the room, I'm afraid.

PRESIDENT VEEDER: It's deliberate.

(Laughter.)

MR. LEGUM: I'm sure that's right. They call

it the hot seat.

PRESIDENT VEEDER: The Respondent had it this morning. It's only fair.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: Is that okay on the Respondent's side?

Sorry. Please continue.

ARBITRATOR ROWLEY: I think the Chairman or President was suggesting that I refer you to, in consideration of his question, the conclusions in Award in RSM and Grenada.

And in that case, there were questions of the standing or ability of privies--that is, shareholders--to all of a corporation that had previously litigated the question, its ability--the ability of the privies, the shareholder, to bring the case, again; and that Tribunal considered that that was not possible. And I think that's what he would want you to--we will want you to consider in responding.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: So to explain, this is RSM

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14:50:47 Grenada Number 2, in which Mr. Rowley was the Chairman of the Tribunal, not to be confused with RSM Grenada Number 1.

ARBITRATOR ROWLEY: No matter what I said, read the case. And if I misdescribed it, can you forgive me or not, but deal with what the case is.

MR. LEGUM: Thank you.

PRESIDENT VEEDER: I think this is a request to--sorry. This is a request to both sides.

I think that's all the questions we had at the moment. So we come to the next stage of your opening.

MR. LEGUM: Very good.

Ms. Dufêtre.

MS. DUFÊTRE: Thank you. In this part of the presentation, I will address the U.S. jurisdictional objection made on the basis of Article 1136(g).

I will show that, contrary to the U.S. assertions, Apotex-Canada Marketing Authorizations are covered investment within the meaning of Article 1139(g).

I start with the text of this provision,

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14:52:36 which you can now see on the screen. The definition of "investment" includes "real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes"...

Apotex Market Authorizations constitute intangible property acquired in the expectation or used for the purpose of economic benefits in the United States.

I need to make a point on semantics before I go further. The U.S., in its Rejoinder, kept referring to Apotex's Marketing Authorizations as ANDAs or "applications."

As explained by Mr. Hay this morning, the acronym "ANDA" stands for "abbreviated New Drug Application." In the industry, the term "ANDA" covers both the application as well as the finally approved Marketing Authorizations. And we explained this distinction in our Memorial at Paragraph 63.

In this presentation, like this morning, when using the term "ANDAs," I refer to the Marketing Authorizations as opposed to the applications, unless

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14:53:54 otherwise stated.

There is no dispute that the Marketing Authorizations issued by FDA are intangible. Similarly, there is no dispute that the Marketing Authorizations are acquired in the expectation and used for the purpose of economic benefit in the United States.

As explained by Mr. Krishnan, Apotex's agent with FDA, any generic drug manufacturer must first obtain a Marketing Authorization in order to market and sell its generic drugs in the United States.

The applications and Marketing Authorizations are specific to United States, and they cannot be used anywhere else in the world.

Ms. Tao explained that when preparing an application for submission to the FDA, Apotex must comply with specific requirements concerning, for instance, bioequivalent studies, and these requirements are specific to the United States and are not the same in other countries.

The only point in dispute in this arbitration is whether Apotex's Marketing Authorizations qualify

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14:55:15 as property under Article 1139(g). The answer is yes.

The term "property" is not defined in the NAFTA, and today it has not given rise to a lot of NAFTA jurisprudence. However, under public international law, the term "property" must be ascribed a broad meaning.

The draft OECD Convention on the protection of foreign property defines "property" as "All property rights and interests, whether held directly or indirectly, including the interest which a member of a company is deemed to have in the property of the company."

The notes and comments to Article 9(c) explain that the definition is in conformity with international judicial practice and shows that it is meant to be used in its widest sense, which includes, but is not limited to, investments.

The draft Convention was endorsed by a resolution of the Council of the OECD in 1967, and thus it represents State practice.

Likewise, the Iran-U.S. Claims Tribunal adopted a broad interpretation of the term "property"

14:56:36 in the Algiers Accords. That Tribunal confirmed that property includes shareholder rights, contractual rights, and other immaterial rights.

I refer the Tribunal to Paragraph 357 of the Memorial and Footnote 515, which collects cases supporting this proposition.

The three NAFTA Parties each have a broad definition of "property" under the domestic law. And here, again, I refer the Tribunal to Paragraphs 359 to 365 of Apotex's Memorial, where the relevant authorities under U.S. law, Canadian law, and Mexican law are discussed.

In the Memorial Apotex demonstrated that its Marketing Authorizations constitute intangible property within the meaning of Article 1139(g) for six main reasons.

First, FDA's own regulations recognized that a pharmaceutical company may own an ANDA, whether finally approved or tentatively approved, and that the ANDA can be transferred for consideration.

Second, on the market ANDAs are regularly bought and sold for substantial amount of money, like

14:57:56 any other property. And Ms. Tao, for instance, explained that Apotex-U.S. purchased Marketing Authorizations from another pharmaceutical company in 2006. So this is regular practice.

Three, U.S. courts have recognized that an ANDA holder has standing to intervene in a case that might affect its rights.

Four, U.S. courts have also treated access to the U.S. market under an approved ANDA as a protected interest.

Fifth, U.S. case law also shows that the marketing exclusivity afforded to certain ANDA holders is a valuable protected interest which can also be traded.

And, finally, other U.S. Government agencies also treat ANDAs as intangible assets; and more specifically, the Internal Revenue Service treats ANDAs as separate and distinct intangible assets for purposes of the tax code.

Now, the U.S. does not dispute that the U.S. tax authority treats ANDAs as intangible property, but the U.S. noted that Apotex-Canada did not pay U.S. tax

14:59:17 on a sale of some of its Marketing Authorizations.

The U.S., however, does not explain why, in the particular circumstances of that transactions, that sale gave rise to a taxable event in the United States. As a result, whatever implication the U.S. seeks to draw, it is without foundation.

The U.S. does not dispute any of the elements that I have just mentioned, and we show that Apotex's Marketing Authorizations are intangible property within the meaning of Article 1139(g).

Nonetheless, the U.S. maintains that Apotex's Marketing Authorizations do not constitute property within the meaning of that provision. The U.S. argument is without merit.

Let me first quickly address an argument that the U.S. has now abandoned. The U.S. initially claimed that even if Marketing Authorizations are property, they are not property in the territory of the United States. This argument was dropped in the U.S. Rejoinder.

It is indisputable that Marketing Authorizations, which are filed with the U.S. FDA in

15:00:33 order to market and sell products in the United States and not anywhere else in the world, these Marketing Authorizations are necessarily located in the United States.

PRESIDENT VEEDER: Just pausing there, why doesn't that make it a taxable event if such an authorization is then sold and the seller makes a capital gain?

MS. DUFÊTRE: Well, the taxable event or the sale of Apotex's ANDA--I mean, the U.S. has not explained why--

PRESIDENT VEEDER: I'm asking you--

MS. DUFÊTRE: --on a particular transaction--

PRESIDENT VEEDER: Forget their case. This is your case.

MR. LEGUM: Perhaps, Mr. President, your question presumes that there was a capital gain.

PRESIDENT VEEDER: Of course it does. Otherwise, there might be no tax payable.

MR. LEGUM: I'm not a tax lawyer, aside from noting that the facts of that particular transaction might not have involved a capital gain. I can't

15:01:29 really answer it.

PRESIDENT VEEDER: Let's leave it at that for the moment.

MS. DUFÊTRE: Just to finish on the points that the Marketing Authorizations are necessarily located in the territory of the United States: I just note that Apotex, in its prior pleadings, referred to Bayview and other decisions where Tribunals have held that a salient factor of investments is that they are primarily regulated by the law of the host state.

Apotex cited Bayview to show that there can be no dispute that Apotex's Marketing Authorizations are investments located in the United States since they are regulated by U.S. law.

The U.S. now suggests that it is Apotex's submission that ANDAs constitute property because they are regulated by U.S. law, but it is not Apotex's position. Our position is that the fact that ANDAs are regulated by U.S. law simply shows that they are investments located in the territory of the United States.

Now, turning to the core of the U.S.

15:02:47 jurisdictional objection on Article 1139(g), the U.S. makes a series of mistaken arguments that are unsupported.

First, the U.S. mixes up the concept of revocable property interest with that of contingent interest.

Second, the U.S. wrongly argue that revocable intangible property interests are not protected under Article 1139(g).

NAFTA case law does not support the U.S.'s interpretation of Article 1139(g). That was the third point.

Four, the U.S. reliance on the takings clause jurisprudence is also misplaced.

And, finally, the U.S. is also wrong when it claims that revocable rights like exclusivity.

I will go through each of these points one by one.

So, first, the U.S. starting point is that Apotex's ANDAs do not constitute intangible property under Article 1139(g) because ANDAs are mere applications, and even if finally approved, the ANDAs

15:03:59 could be revoked.

The U.S. goes on to say that Apotex's Marketing Authorizations, because they can be revoked, are mere contingent interests and, as such, they cannot be recognized as property under the NAFTA.

The U.S. argument is flawed because Apotex's Marketing Authorizations are not contingent interest but, rather, vested rights. The Tribunal will recall the difference between tentatively approved ANDAs and finally approved ANDAs.

Tentatively approved ANDAs are contingent interest. They are not yet final authorizations, and they do not permit to market in-dispute drugs in the United States.

In contrast, the finally approved ANDAs are vested rights. They are Marketing Authorizations that FDA has granted and which permit the marketing and distribution of the associated products.

The Tribunal will also recall that Apotex's tentatively approved ANDAs are no longer in dispute in this arbitration. Apotex claims only concern finally approved ANDAs; in other words, vested rights.

15:05:17 While the U.S. seeks to blur the distinction between applications and approved Marketing Authorizations, it fails to explain the actual--how the actual authorizations could only be mere contingent interests. They are not. They are vested rights.

Turning to my second point, the fact that the Marketing Authorization can be revoked on specific statutory grounds does not make them any less protected than any other property under Article 1139(g).

The U.S. argument that revocable interests could not qualify as investment does not accord with the text, context, and objective and purpose of the NAFTA. I start with the text.

As noted by the U.S., the NAFTA does not list intellectual property rights, such as licenses, authorizations, and permits, as investments under Article 1139. But Article 1139, then, does not--this provision does not expressly exclude such interests either. In fact, licenses, authorizations, and permits are covered as investment pursuant to the

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15:06:35 definition of "intangible property" in Article 1139(g).

The context of Article 1139(g) also sheds light on how the term intangible property's provision should be interpreted.

I will look at two specific provisions that form part of the context of Article 1139(g), specifically, Article 1110 and Article 1108.

First, Article 1110. This is the provision on expropriation. Paragraph 7 of that article, which you can now see on the screen, provides that this article does not apply to the revocation of intellectual property rights to the extent that such revocation is inconsistent with Chapter 17.

Article 1110, Paragraph 7, recognizes that intellectual property rights are revocable. Under this provision, the NAFTA Parties are not obligated to compensate for expropriation of a license concerning IP rights, provided that the revocation was in accordance with Article--with Chapter 17 of the NAFTA.

Au contraire, if the license is revoked in a way that is inconsistent with the Chapter 17, the

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15:08:04 license holder will be able to seek compensation for unlawful expropriation under Article 1110.

Article 1110, Paragraph 7, would have no reason to exist if the U.S. interpretation was correct. If revocable property rights were not investments under Article 1139, the investment chapter, including Article 1110, would not apply to those revocable rights in the first place.

If the U.S. interpretation were followed, Article 1110, Paragraph 7, would have no reason to exist. To put it slightly differently, if the U.S. interpretation was followed, it would render Article 1110, Paragraph 7, ineffective, and this would be contrary to one of the basic tenets of treaty interpretation, namely FET.

The U.S. does not respond to Apotex's argument on this point. Instead, the U.S. pretends that Apotex's argument is that "all revocable intangible rights are investment." But the U.S. fails to explain, however, why revocable intangible rights can never be investments. The U.S. contention is incompatible with the NAFTA.

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15:09:29 Second, looking at Article 1108, it is also part of the context of Article 1139(g). So that specific provision that you can now see on the screen permits limited exceptions to certain protections of Chapter 11, such as National Treatments.

These exceptions are set out in the U.S. schedule to Annex 1 to the NAFTA. And to give one example, the U.S. excluded from the coverage of Article 1102 on National Treatment certain customs broker licenses issued under specific provision of U.S. law. It is important to understand that this type of licenses under U.S. law is revocable.

Again, if revocable interest did not fall within the definition of "investments" under Article 1139(g), which is the U.S. position, there would have been no need for the U.S. to make an exceptions for customs broker licenses. And yet, the U.S. expressly made this exception.

The U.S. has failed to respond to Apotex on that point, and, instead, the U.S. makes the general proposition that a license may be required for the establishment and conduct of an investment.

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15:11:00 That may well be the case in some circumstances, but it does not change the fact that licenses or permits may themselves be an investment.

These are two examples that show that the U.S. interpretation that revocable intangible property--sorry--revocable property interests are not covered by Article 1139(g). That interpretation cannot be reconciled with the context of the provision.

Finally, turning to the object and purpose, the U.S. interpretation also does not accord with the object and purpose of the NAFTA.

The Treaty's objectives include providing adequate and effective protection and enforcement of intellectual property rights in the territory of the State Parties. The objectives of the NAFTA also include increasing substantially investment opportunities in the territory of the State Parties.

Because intellectual property rights are revocable, the U.S. interpretation of the Article 1139(g) would exclude investment protection for such intellectual property rights. This result

would be contrary to the stated objectives of the NAFTA.

To conclude, based on the text, context, object, and purpose of the NAFTA, revocable intangible property interests do qualify as investments within the meaning of the Article 1139(g).

I will now turn to my third point, which is that the NAFTA jurisprudence does not support the U.S. argument that revocable interest cannot be under the NAFTA.

In the Grand River case, the Tribunal held that a U.S. trademark constituted an investment for the purposes of Chapter 11. Tellingly, trademarks are revocable under U.S. law and the relevant Legal Authority is in the record. It is CLA-558.

Despite the fact that trademarks are revocable under U.S. law, the Grand River Tribunal nevertheless recognized that a U.S. trademark was protected investment for purposes of the NAFTA.

I now turn to my fourth point. The U.S. has also argued that revocable interests do not constitute property under the takings clause of the U.S.

Constitution.

As a preliminary matter, I note that the meaning of the "property" under the U.S. Constitution is irrelevant. What is relevant for our purposes is the meaning of "property" under the NAFTA, not the U.S. Constitution.

In any event, the U.S. failed to explain why the takings clause jurisprudence would be more appropriate than due process jurisprudence.

By way of background, the Fifth Amendment to the U.S. Constitution refers to property in two different clauses: the due process clause and the takings clause. But the U.S. has relied only on case law developed in the context of the takings clause, and the U.S. has entirely disregarded the import of the due process clause jurisprudence.

The U.S. approach is odd given that there is no taking at issue in the present case. None of the Marketing Authorization of Apotex-Canada has been revoked. This fact is undisputed.

But this morning, I noted during Ms. McLeod's presentation that she mentioned that one of the

grounds for revocation of approved ANDAs was the noncompliance with cGMP. But, again, in our case there was no revocation of Apotex's ANDAs. They remained in full effect.

So, going back to the point on the takings clause jurisprudence, perhaps one of the reason why the U.S. has chosen to focus on the takings clause rather than the due process clause is that the jurisprudence under the takings clause is given a more restrictive reading of the concept of property.

But again, in any event, the takings clause is an apposite in this case, and all that matters is the interpretation of the term "property" under the NAFTA.

I will now make my fifth and final observation, which is that the U.S. is also wrong when it argues that rights can be revoked by the Government under limited circumstances, and that it would deprive the property owner of exclusive possession or control.

I simply note that any property interest can be revoked by the Government under certain circumstance, and the U.S. does not dispute this

point.

The fact that an interest can be revoked does not mean, however, that the revoked property right was not exclusive in the first place. For instance, under U.S. law, the owner of real property enjoys exclusive ownership, and yet its title can be revoked by adverse possession.

Mr. President, Members of the Tribunal, for the reasons set out in Apotex Memorial Reply and Rejoinder on Jurisdiction, Marketing Authorization owned by Apotex-Canada and owned by Apotex Holdings indirectly, these Marketing Authorizations constitute intangible property within the meaning of Article 1139(g), and they are investments under the NAFTA.

That concludes my presentation on this section. And if there are no further questions, I'll turn the floor to Mr. Legum.

PRESIDENT VEEDER: Yes.

ARBITRATOR ROWLEY: I have a question for Claimants, but it's also for Respondents, and it doesn't have to be answered now. If you're in a

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15:17:58 position to answer it now, Claimants, go ahead. Respondents can do it in due course.

In looking at Apotex I and II, even if we were not to find it to constitute res judicata, we--or should we not find it, we would still, perhaps, find it useful to look at it in terms of analysis.

And one of the points that seem to come out to me in the analysis of that Tribunal--and it's illustrated at Paragraphs 208 and 217 in particular, but it may be illustrated elsewhere--is that that Tribunal seemed to be persuaded as to the--whether the applications for ANDAs in those cases constituted an investment because of the nature of Claimant in that case.

At 208, it spoke of the property is not an investment if, as here, it merely supports a cross-border sale. And at 217, the Tribunal said whilst an ANDA itself may not be, in strict technical terms, an export or import license, it operated in this case in precisely the same way.

And my question for the Parties is this: Is the question of whether something constitutes property

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15:20:24 to be determined only through the eyes of the investor, or is it to be determined by the quality of the--I call it an asset in loose terms--in whoever's hands the asset may be?

And so at some stage, I would like to hear from the Parties whether an approved ANDA in this case in the hands of a U.S.-based pharmaceutical manufacturer might be an investment while it would not be an investment in the hands of a foreign manufacturer.

MR. LEGUM: Thank you, Mr. Rowley. We will consider that question and not provide an answer just yet, but after having reflected upon it for a little while.

PRESIDENT VEEDER: That was it. Thank you very much. We'll now move on to the next stage. But at some stage, we need to take a break for the shorthand writer. So we leave it to you to decide when it's most convenient.

MR. LEGUM: The next segment is about 35 minutes long, so it probably makes sense to take a break now.

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15:21:57 PRESIDENT VEEDER: Take a break now. Let's take 15 minutes now and come back at 20 to 4:00. Thank you.

(Brief recess.)

PRESIDENT VEEDER: Mr. Legum, as we understand it, we're now starting on Slide 67 on the last part of your submissions on jurisdiction.

Don't worry about the details. I'm just querying how--whether we're likely to get to a witness. How you're doing.

MR. LEGUM: Oh. So, our thought, Mr. President, is to finish our presentation on jurisdiction, to then go into our discussion of the Legal Standard under Articles 1102 and 1103 of the NAFTA and the criteria for selecting comparators today and then at that point we'll break for the day and begin first thing tomorrow morning with witness examination.

PRESIDENT VEEDER: So no witness today?

MR. LEGUM: That's our thinking. Yes.

PRESIDENT VEEDER: Okay. You have the floor.

MR. LEGUM: Mr. President, Members of the

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15:40:18 Tribunal, I will now address the United States objection that Marketing Authorizations are not investments within the meaning of Article 1139(h) of the NAFTA. This is the paragraph that defines "investment" to include "interests arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory."

My presentation will have five parts. I will begin with some general observations on the text of Article 1139(h). I will show that Marketing Authorizations are interests within the meaning of this provision. I will then demonstrate that these interests arise from the commitment of capital or other resources.

I will show that Apotex committed these capital and resources to economic activity in the territory of the United States, and I will conclude by addressing whether Article 1139(h) requires the capital and resources to be located in the United States at the time of the commitment or whether foreign capital and resources qualify.

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15:41:36 So I begin with the text which is on the screen. Under this provision, the investment is the interest. The term "interest" is different from the term "property" used in Article 1139(g). By using a different term, "interest," in Paragraph (h), the NAFTA Parties clearly intended to cover things that did not rise to the level of property. Paragraph (h) helpfully provides examples to illustrate what the NAFTA Parties had in mind. Each of these two examples refers to Contracts. Contracts are not considered to be property under the laws of some legal systems.

To qualify under Article 1139(h), the interest must arise from a commitment of capital or resources. The capital and the resources in this provision are not the investment. As just noted, the interest is the investment. The capital and the resources, under Article 1139(h), must give rise to the interest. Nothing in the provision suggests that the capital and resources must independently qualify as an investment.

To give rise to a qualifying interest, the act required is a commitment. The examples, here

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15:43:23 again, are helpful. One of the examples is of a "Turnkey Contract." A Turnkey Contract to construct a power plant between a Canadian firm and a U.S. utility firm involves a commitment. The Canadian firm, by signing the Contract, commits that it will devote resources and, perhaps, capital to constructing the power plant. At the time the Contract is signed, usually no resources or capital will yet have been devoted to the project. Usually, the Contract comes first, then comes the work. The commitment in the Contract that the resources will be deployed is enough.

Finally, the commitment must be to economic activity in the host State. If the power plant in the example I just gave was to be built and operated in Ecuador, it would not qualify.

With this background, I turn to the first element of Article 1139(h), interests. Apotex's Marketing Authorizations clearly constitute interests of Apotex-Canada and indirectly controlled interests of Apotex Holdings.

As noted earlier by Ms. Dufêtre, Apotex's

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15:45:05 Marketing Authorizations have all of the characteristics of property. They can be owned under FDA regulations. They can be and are regularly bought and sold. They are recognized as intangible assets. And the courts recognize the standing of the holders of those Authorizations to intervene in court to protect their property.

Now, Apotex submits that all of these factors demonstrate that Apotex's Marketing Authorizations constitute property within the meaning of Article 1139(g). However, even if they do not rise to the level of property, they clearly constitute interests within the meaning of Article 1139(h). Indeed, the U.S. does not challenge this point. In fact, it acknowledges in its Rejoinder that U.S. courts have recognized ANDAs to be interests sufficient to give their owners standing.

I come now to my third point. These interests, the Marketing Authorizations, arise from the commitment of capital or other resources. There are several distinct categories of resources that Apotex commits with its Marketing Authorizations.

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15:46:34 First, Apotex commits valuable proprietary information and know-how to developing, preparing, and obtaining its Marketing Authorizations. Every Authorization to market a new drug is the result of substantial research and development, some of it in-house, some of it performed by Contract research organizations. The application for such Authorization is the fruit of these resources. It reflects proprietary information concerning the drug's formulation, its development, testing, and manufacturing. No application for such a Marketing Authorization can be developed without a very substantial contribution of capital and other resources.

The record shows that this was the case for Apotex's Marketing Authorizations, and I refer the Tribunal here to the Witness Statements of Bernice Tao and Kiran Krishnan.

Second, Apotex, like other owners of Authorizations to sell a drug in the United States, commits to devote substantial resources to meeting FDA requirements for periodic and other reporting

concerning the drug. In order to meet its reporting commitment, Apotex has a full-time team of six employees in Florida, led by Mr. Kiran Krishnan, who, as I just mentioned, submitted a Witness Statement in this arbitration. This team in Florida is dedicated to filing and fulfilling FDA post-approval requirements which are quite substantial.

So for each one of the dozens of Marketing Authorizations that Apotex owns, Apotex is obligated to submit annual reports, drug safety reports, and to continuously update its drug labels and patient information leaflets.

Third, in order to give value to its Marketing Authorizations, Apotex pays [redacted] annually for patent litigation to open up the market and make it more competitive.

Now, the U.S. does not dispute Apotex's showing that its Marketing Authorizations arise out of a commitment of capital and other resources. Instead, it disputes a series of positions that Apotex has not advanced and repeatedly claims that the Apotex I and II Tribunal addressed arguments advanced in this

arbitration that were never presented there.

In its Counter-Memorial, the U.S. argued at length that cross-border research Contracts, funding for litigation, and reporting required for Marketing Authorizations did not constitute investments. In its Reply, Apotex observed that it had never argued that any of these activities constitute an investment. Instead, Apotex made clear its position that these activities constituted resources that Apotex committed to give rise to the interests that its Marketing Authorizations represent.

We noted that the ordinary meaning of the term "resource" is "source of supply or support, an available means." That is precisely what these activities are, a source of supply or support for the Marketing Authorizations. The U.S. argument that these activities are not investments in themselves misses the point.

In its Rejoinder, the U.S. offered no response on this argument. There is no response.

The U.S. Rejoinder places great reliance on the Award in Apotex I and II, arguing that the

Tribunal decided the issues concerning Article 1139(h) presented before this Tribunal. This contention is surprising.

As the Tribunal can see from the text on the screen, the Apotex I-II Tribunal made clear that the arguments before it on Article 1139(h) were undeveloped. In that case, Apotex did not advance an independent argument under Article 11139 (h). Instead, it said that those arguments were to be treated as part of its submissions under NAFTA Article 1139(g).

PRESIDENT VEEDER: Let me interrupt you.

MR. LEGUM: Yes, please.

PRESIDENT VEEDER: That may be so, but nonetheless, if we read the Award from Paragraph 226 to 240, we do see a fairly careful analysis of Apotex's possible case under 1139(h), and at some stage, we need to be taken through as to what you say about their findings.

MR. LEGUM: Yes, please.

The arguments that are advanced in this Tribunal were not advanced before that Tribunal, even

in the very different context before it of applications rather than Marketing Authorizations. The issues before this Tribunal were not actually litigated and determined in that case.

Moreover, the Award in Apotex I-II does not support the specific points that the U.S. relies on it for. Apotex I and II did hold that litigation expenses do not constitute investments, but that is not the argument presented here, as I've already noted.

That Tribunal did not address the showing made here that the [redacted] Apotex pays in patent litigation in the U.S. every year constitute resources committed to increasing the value of the Marketing Authorizations.

Similarly, Apotex I-II found that proprietary information cannot transform mere applications into investments. But, again, Apotex's position is that know-how and proprietary information constitutes resources committed to giving rise to the Marketing Authorizations and not investments in and of themselves.

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15:53:27 And this case deals with--this case here deals with scores of Marketing Authorizations exploited profitably for years. By contrast, Apotex I-II dealt exclusively with two applications for discrete products. We submit that the reliance on Apotex I-II is misplaced.

In sum, the record shows that Apotex committed substantial capital and resources to its Marketing Authorizations. That capital and those resources need not constitute investments in and of themselves. The record establishes, we submit, this element of Article 1139(h).

I come now to the fourth element of Article 1139(h), economic activity in the host State. This part of my presentation will be brief because the record leaves little doubt on this element.

An ANDA, as Ms. Dufêtre observed, approved by the FDA authorizes its owner to market the covered products in the United States and nowhere else in the world. That is what an FDA drug Market Authorization does. It authorizes the sale of the drug in U.S. territory. Apotex's witnesses submitted Witness

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15:54:55 Statements on this point. There is no doubt that the commercial sale of drugs is a form of economic activity.

I arrive now at the fifth and final part of my presentation, the location of the capital or other resources at the time of the commitment.

As the Tribunal will recall from the pleadings, the text of Article 1139(h) presents an interpretive puzzle. In the authentic English version of the text, there are two references to the territory of the host State, while in the authentic Spanish, there is only one. This gives rise to a textual question on whether the capital and other resources need already to be in the host State at the time of their commitment or whether foreign capital qualifies.

I will turn to this interesting question in a moment.

But before doing so, I would like to note that this question is not necessarily posed in this case. This is because it is undisputed that Apotex committed resources already located in the U.S. to its Marketing Authorizations. The U.S. does not dispute

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15:56:21 that the seven-person team in Florida devoted to meeting the reporting obligations required by Marketing Authorizations constitute a commitment of resources.

ARBITRATOR ROWLEY: Did you say six earlier?

MR. LEGUM: Six people.

ARBITRATOR ROWLEY: Six full-time employees. Is there one not full-time?

MR. LEGUM: Six full-time employees led by Mr. Kiran Krishnan, who submitted a Witness Statement in this case. So six plus one is seven.

Yes, please.

ARBITRATOR CROOK: Sorry; so this is a--the seven employees are a cap--commitment of capital and resources by whom?

MR. LEGUM: They're a commitment of capital and resources. They're employed by Apotex-U.S.

ARBITRATOR CROOK: I understand that.

MR. LEGUM: Clearly, they are--so I'll come to this question in a moment, but two points, which, again, I'll repeat in just a second.

First is that Article 1139(h) requires a

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15:57:26 commitment of capital resources. It does not provide that the entity that commits the capital and resources must be the same entity that owns the Marketing Authorizations.

Under the NAFTA, Apotex Holdings is the controller and indirect owner of both Apotex-U.S. and of the Marketing Authorizations. So if it matters what the entity is, then in this case the investor is the controller of both the entity that owns the Marketing Authorizations and the entity that is committing the capital and resources. So it can be viewed as a commitment of capital and resources by Apotex Holdings in this sense.

The argument that the U.S. advances concerning these resources is the one that Mr. Crook just raised, which is to challenge Apotex-Canada's contribution to them.

On the law, as I've just mentioned, Article 1139(h) does not require the owner of the interest to be the same as the entity that commits the resources. Article 1139(h) requires only that the interests arise out of a commitment of resources to economic activity

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15:59:08 in the host State. Nothing in it excludes a scenario where one company in a corporate group owns the interest and another contributes the resources.

This is, I would note, not an unusual scenario with respect to intellectual property, where increasingly the approach by multinational companies is to have one specific entity that owns the intellectual property rights and other entities that are operating entities.

Factually, the U.S. position is unfounded as well. The U.S. argument boils down to its assertion that under the 2005 Services Agreement between Apotex-Canada and Apotex-U.S., Apotex-U.S. makes payments to Apotex-Canada and not vice versa. So it is accurate to say that under that Agreement, it's Apotex-U.S. that makes payment to Apotex-Canada in return for Apotex-Canada's support of Apotex-U.S. in the form of IT services and other contributions that I'll come to in a little while.

The fact that consideration is paid in return for a contribution, however, does not diminish the importance of that contribution.

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16:00:53 In our Reply, we pointed to specific examples of contribution of capital and other resources that are typical in the business world. For example, the issuance of shares to a Shareholder in return to a capital contribution to a company, or the signing of a Shareholder loan acknowledging the loaning of money by a Shareholder to a company.

In each of those instances, the Shareholder is making a contribution of capital or other resources to the company in a fairly classic and common way. But, at the same time, of course, it is receiving consideration in the form of equity securities in the case of share issuance, or a Shareholder loan document or documentation of the Shareholder loan in the case of a Shareholder loan.

Just because there is consideration for a contribution does not mean that there has been no contribution, and there is no response that we've heard from the United States on this point.

Please.

ARBITRATOR ROWLEY: I just have one little question here. I'm having a bit of trouble with that

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16:02:22 proposition. When I look at--starting first with the definition of "Investor of a Party," it means a Party or a State enterprise thereof or a national or an enterprise--in this case enterprise--of such a Party that seeks to make, is making, or has made an investment. And I look at that to give context to the interest.

If the investment is an interest, has made an investment, and that is an interest--and I look at interest arising from the commitment of capital. I mean, how has it got the interest, and do I look at these words to say the commitment of capital or other resources have led to the interest and that is what has been made by the investor?

It's something that I think needs to be addressed in this point as to where the commitment comes from.

MR. LEGUM: All right. Well, we will consider that point and address it later on in our presentations, then.

Thank you.

So our submission is that the record shows a

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16:04:13 contribution of Apotex-Canada to Apotex's U.S. in the form of administrative, financial, accounting, and IT service, among others. Clearly, Apotex-Canada has contributed resources to Apotex-U.S. that supported resources giving rise to Apotex's Marketing Authorizations. In short, the record shows a commitment of resources in the U.S. to the Marketing Authorizations owned by Apotex-Canada and controlled by Apotex Holdings.

Now, with this preliminary point in mind, I will now address the textual interpretation issue.

The U.S. argues that the capital and other resources that Apotex committed to its Marketing Authorizations at issue here must have been in the United States before being so committed. In other words, the U.S. position is that foreign capital and other resources do not qualify for purposes of Article 1139(h).

The text, context, and preparatory work of Article 1139(h) as well as the object and purpose of the NAFTA lead to a contrary conclusion. Apotex addressed this point at Paragraphs 377 to 393 of its

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16:05:33 Memorial, and I will summarize it here.
So the by-now familiar English text of Article 1139(h) is on the screen. It is notable that the Spanish version of the chapeau in Paragraph (h) reads differently from the English version. So what we did is we took the Spanish and had a certified translation done back into English that the United States has not challenged. So you see it on the screen, the original Spanish version, and the translation into English of the original Spanish version.
ARBITRATOR ROWLEY: Do we see that on a slide somewhere?
MR. LEGUM: Yes. It's Slide 77.
ARBITRATOR ROWLEY: Thank you.
MR. LEGUM: So the translation of the Spanish reads "an interest resulting from capital or other resources devoted to the performance of an economic activity in the territory of another Party." And then it goes on to list examples.
The Spanish version, as you can see, contains only one reference to the territory of the Party,

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16:07:07 which appears twice in the English text. So you have now on the screen the original English version and then the English translation of the original Spanish version. In both the Spanish and the English texts, it is clear that the capital or other resources must be devoted to economic activity in the relevant territory.
The English text, however, is unclear as to whether the capital or other resources must be committed or devoted--to use the term from the Spanish--to the territory of the other Party or whether the capital or other resources must be located in the territory of the other Party at the time of their commitment.
Under NAFTA Article 2206, the English, French, and Spanish texts of the Treaty are equally authentic.
Under Article 33(4) of the Vienna Convention, "When a comparison of the authentic texts discloses a difference of meaning which the applications of Articles 31 and 32 does not remove, the meaning which best reconciles the texts having regard to the object

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16:08:25 and purpose of the Treaty shall be adopted."
The text of the relevant NAFTA provision, its preparatory work, as well as the object and purpose of the Treaty, lead to the same conclusion; that the capital and other resources do not have to be located in the host State before they are committed to the interests at issue.
I start with the text. So as noted earlier, Article 1139(h) helpfully provides two examples of the types of interests it encompasses. Neither of these examples suggests that the capital or resources of the investor must be in the host State's territory before the Contract at issue is signed. Such a requirement would be contrary to the economic reality of many business deals.
Now, let me pause for a moment to consider one of examples listed: Production-sharing Contracts. These are familiar from the upstream oil and gas sector. A production-sharing Contract often is entered into by international oil companies to provide compensation for the substantial resources required to explore, identify, develop, and bring into production

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16:09:51 often difficult-to-access petroleum resources.
The Contract here is the interest within the meaning of Article 1139(h). The international oil company is required to prepare geological surveys of the relevant area, analyze the data, make sophisticated judgments as to where best to conduct exploratory drilling, what technology to bring to bear, design, transport, drilling equipment, and implement one or more exploratory wells and then, if and when reserves are found, design and implement a plan to drill a production well and extract the oil or gas for commercial exploitation.
Now, this a classic form of investment. It is perfectly understandable that the NAFTA Parties would wish to include production-sharing Contracts as an example of the interest contemplated by 1139(h).
Let's consider this example a bit further. At the time the Contract is signed, the international oil company may not have any operations in the host State. It may not have any personnel or any equipment in country. By signing the Contract, it is committing to bring its resources to bear in economic activity in

16:11:15 the host State in the future. But at the moment of signing, there may be no resources at all already located there.

Many of the key resources committed may be at the oil company's headquarters, those required to analyze the geological surveys, design the drilling program and technology and production plans. Most of the resources at issue will not themselves qualify as investments.

Drilling an exploratory well, for example, on someone else's property, is an activity necessary to give value to the interests created by the Contract. It is not an investment in itself, and it may or may not actually result in enhancing the value of the investment.

But regardless of where the resources were originally located, it is clear that the Contract arises from a commitment to economic activity in the host State.

Now, the context of Article 1139(h) in the form of the example provided is, thus, consistent with the view that the capital and resources need not be in

16:12:26 the host State at the time of commitment.

Now, I'm going to move on to the object and purpose of the NAFTA, but before I do so I want to note that the facts here are analogous to the those of production-sharing Contract example.

Here, Apotex had resources both within and without the host State at the time it submitted its applications for Marketing Authorizations. Some, like those used to research and develop the processes used to produce the drug were located at Apotex-Canada headquarters in Toronto. Some, like those used to follow up on the application after approval and prepare the reports required to maintain the Marketing Authorizations, some of these were located in the host State at Apotex-U.S.' offices in Florida.

Many of the resources brought to bear would not themselves constitute investments, like the funding of patent litigation to enhance the value of Marketing Authorizations by opening up the market. Like production-sharing Contracts, the interests represented by Apotex's Marketing Authorizations arose from Apotex's commitment of resources to economic

16:13:45 activity in the United States. They were investments under Article 1139(h).

So I close that parenthesis and turn now to the object and purpose of the NAFTA. Now, the relevant provision, Article 1102(1) is now familiar because this is not the first time that we have referred to it. And one of the stated objectives is to "increase substantially investment opportunities in the territories of the NAFTA Parties."

Now, this implies attracting investment from an investor of one NAFTA Party into the territory of another NAFTA Party.

Now, as the U.S. argued in this arbitration based on the Bayview Award, the NAFTA "can only be sensibly considered as referring to, opportunities for foreign investment in the territory of each Party made by investors of another Party."

Apotex agrees. It would make no sense for the NAFTA Parties to exclude foreign capital or resources from those eligible to give rise to a qualifying interest under Article 1139(h).

The U.S. reading of Article 1139(h) would,

16:15:19 however, exclude foreign capital and resources from eligibility, even if it is committed to economic activity in the host State.

The U.S. position would defeat this objective of the NAFTA. Indeed, under the U.S. view, Article 1139(h) could create no new flow of investment into the host State. It would merely allow capital and resources already present in the host State to be packaged in a different form.

By contrast, reading Article 1139(h) to allow new capital or resources to be devoted to economic activity in the host State is consistent with NAFTA's objective of substantially increasing investment.

I come now to the preparatory work of this provision. That preparatory work, the "travaux preparatoires," further supports Apotex's submissions.

The August 4 1992, negotiating draft, one of the drafts that preceded the final version of the article 1139(h), is now on the screen. It reads as follows: "Interests arising from the commitment of capital or other resources in or into the territory of another Party to economic activity in such territory."

16:16:59 This text very clearly provided that the investments could be made in or into the host State. In other words, the text made it clear that the investment could be contributed from either within or without the host State.

Now, this was agreed text at this point. There are no brackets or other comments that marked the words "or into."

The following day of negotiations, the text was revised to place brackets around the words "or into." And you have the text from the August--well, whatever the next draft was--August 11, 1992, draft on the screen. So the words "or into" are now in brackets with a footnote. And the footnote says, "checking to see if necessary."

Now, this note represents the negotiators' intent to check if it was necessary to include the two closely related prepositions "in" and "into" in the same clause, especially that "in" is a broader preposition and typically covers "into."

The informal note stating that the Parties were checking if the second preposition was necessary

16:18:27 does not justify a conclusion that the drafters intended to change the substance of the provision; in order to avoid using redundant words, they were simply checking which would be a better formulation.

Subsequently, the bracketed words "or into" were removed in the lawyers' revision of August 27, 1992.

Now, all decisions on substance in the negotiation of the NAFTA were made by the policymakers on the negotiating teams.

The lawyers' revision, in principle, was only to address style and consistency. The fact that the words were deleted by the lawyers' revision also shows that there was no intent to change the content of the definition.

Thus, the text, the context, the object and purpose, and the preparatory work of the NAFTA all concord, capital and resources outside the host State at the time of commitment qualify under Article 1139(h). The U.S. argument to the contrary is without support.

Now, before concluding on Article 1139(h), I

16:19:50 note that the U.S. Rejoinder asserts that there is an agreed interpretation of this provision by the three NAFTA Parties. It cobbles together this supposed agreement from a variety of different sources. We submit that a review of the texts referenced by the U.S. does not support an agreement between the NAFTA Parties that is relevant to any of the points presented here. And I would refer to the Tribunal to Paragraph 121 of Apotex's Rejoinder on Jurisdiction, which demonstrates that the various sources address points different from that pertinent.

So, in conclusion, all of the elements of Article 1139(h) were satisfied here. The Marketing Authorizations clearly are interests. They arose from the commitment of capital or other resources to economic activity in the United States.

Mr. President, Members of the Tribunal, that concludes our Case-in-Chief on jurisdiction. I would now turn to the first part of our discussion of National Treatment and Most-Favored-Nation Treatment unless there are questions.

ARBITRATOR CROOK: I wonder if you have any

16:21:11 enlightenment for the Tribunal on the argument that was advanced by the Respondent to the effect of the French text, which is also an equally authentic text is consistent with the English; and if that is so, if we have--it is Page 240--Paragraph 248 of the U.S. Counter-Memorial, if it is, indeed, the case that the French and English texts conform, does the Vienna Convention rule then dictate that the one text out of three that does not have the relevant language is the one that controls?

MR. LEGUM: Well, so two points on that. First--and perhaps things have changed, but my understanding is that there has never been an agreed authentic French version of the NAFTA notwithstanding the language in Article 2206.

And, in fact, the version that's available on the Web site, if you read French, is full of a number of strange statements. But perhaps our colleagues at the State Department can shed light on whether that has been rectified in recent years.

That being said, Article 33(4) of the Vienna Convention does not adopt a rule of numbers where,

looking at more than one version of the Treaty--where there are more than one version of a Treaty, one authentic version or two authentic versions are better than one. And my understanding is that the French version was prepared after the Spanish and English versions of the Treaty were negotiated.

PRESIDENT VEEDER: No more questions at this stage.

MR. LEGUM: We'll need to take a two-minute break just to change the slides.

PRESIDENT VEEDER: Let's take five minutes. There's never been a two-minute break.

MR. LEGUM: Okay. Five minutes.

(Brief recess.)

PRESIDENT VEEDER: Let's resume.

MR. LEGUM: Mr. President, Members of the Tribunal, we will now address Apotex's claims under Articles 1102 and 1103 of the NAFTA. We'll demonstrate that the U.S. breached each of these provisions on National Treatment and Most-Favored-Nation Treatment.

Now, these claims are about differential

treatment. Apotex was treated less favorably than U.S. and third-country-owned investors and investments in like circumstances.

In short, FDA placed Apotex on Import Alert for two years while it did nothing against the relevant comparators. FDA did not impose any kind of market ban on these comparators. In fact, it took no enforcement action at all against these companies despite the fact that FDA found, at their manufacturing facilities, cGMP violations that were similar to if not more serious than the violations it found at Signet and Etobicoke.

Our presentation on National Treatment and MFN Treatment will be divided into four main parts. First, I will start with the law and review the legal standards set out in Articles 1102 and 1103. Second, my colleague, Ms. Dufêtre, will say a word on the criteria used for selecting comparators. Third--and we'll likely pick up with this part of our presentation tomorrow--we will show that on this record, each comparator selected by Apotex was in like circumstances and received more favorable treatment

than Apotex. And, finally, we will explain why the comparators selected by the U.S. are not apt.

Let's start with the legal standards in Articles 1102 and 1103. I begin with the text.

If we look at the first paragraph of Article 1102 and 1103, the focus in each is on treatment accorded by a State Party to investors with respect to their investments. If we look at the second paragraph of Article 1102 and 1103, the focus is on investments of investors of another Party. The first step is to identify the investors and the investments at stake and those investors and investments to be used as the comparators.

Now, in our case, the investors are Apotex Holdings and Apotex-Canada. Their investments consist of two things, the enterprise, Apotex-U.S., and the Marketing Authorizations held by Apotex-Canada. Apotex Holdings is an investor with respect to each of these investments. Apotex-Canada is also an investor with respect to the Marketing Authorizations.

Now, to be eligible for the comparison contemplated by Articles 1102 and 1103, a comparator

must also qualify as an investor or an investment under the NAFTA. The comparison required is of investors of another NAFTA Party, or their investments, here Apotex, and investors of another nationality, or their investments.

I'll now turn to the nationality of the comparators. Now, Articles 1102 and 1103 are drafted in a similar fashion. The only difference between these provisions is the nationality of the comparators.

Article 1102 is the provision on National Treatment. As such, the investors and investments at stake must be compared with investors that have the nationality of the host State or investments of investors with that nationality. In other words, Apotex Holdings and Apotex-Canada and their investments in the U.S. need to be compared with investors of the U.S. nationality and investments which are U.S.-owned.

Article 1103 is the provision on Most-Favored-Nation Treatment. Here, Apotex Holdings and Apotex-Canada and their investments must be

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16:34:44 compared with investors which have the nationality of a third Party and with investments that are third-country-owned.

In our case, nationality of a third Party means any nationality except Canadian, which is the nationality of the investors, or American, which is the nationality of the host State.

Under the NAFTA, a single Measure directed to a single investment can breach both Articles 1102 and Article 1103. This is because of the definition of "investment" under Chapter 11. Let me briefly explain.

Under Article 1139, the term "investment of an investor of a Party" is defined as "an investment owned or controlled directly or indirectly by an investor of such Party"...

It is perfectly possible for an investment directly to be owned by a U.S. subsidiary where the ultimate parent company has a different nationality. Let's say Swiss. In this instance, Article 1102 will apply to the investment because it is U.S.-owned. Article 1103 will also apply to it because indirectly

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16:36:18 it is Swiss-owned.

If a Measure grants that investment treatment more favorable than that afforded to a covered investment in like circumstances, the Measure will at the same time violate each of Articles 1102 and 1103.

Some of the comparators in this case present precisely this scenario. For this reason, the Parties have largely addressed Articles 1102 and 1103 as a unitary analysis in their pleadings, and this will be the approach we follow today.

We simply note that in order to make the text easier to read in the discussions that will follow, we're using the text of Article 1102, but obviously the same applies for Article 1103 with the nationality of the comparator being different.

Having identified appropriate investors or investments as comparators, a Claimant needs to show two things to prevail: First, as Claimant Apotex needs to establish that the treatment accorded to Apotex and its investments was accorded in like circumstances with the treatment accorded to the comparators; second, Apotex needs to prove that the

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16:37:49 treatment accorded Apotex and its investments was less favorable than that accorded to the comparators.

The Cargill Tribunal described National Treatment and Most-Favored-Nation Treatment as a two-step analysis. And you have the relevant language on the screen.

In the first step, the Claimant needs to demonstrate as an investor that it is in like circumstances with the investor of another Party--here the U.S.--or of a non-Party. Alternatively, the Claimant needs to demonstrate that its investment is in like circumstances with the investment of another Party or of a non-Party.

In the second step, it must be shown that the treatment received by the Claimant was less favorable than the treatment received by the investor or investment in like circumstances.

Now, if I were to use a mathematical formula to illustrate this two-step analysis, here is what it would look like. The circumstances must be like. They must be about the same, approximately equal. The treatment must be less favorable. So there are two

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16:39:08 different elements to this analysis. Each element must have a value that is different from the other element.

Now, NAFTA jurisprudence has elaborated on Articles 1102 and 1103 in several pertinent respects. First, it is now clear that a Claimant need identify only one comparator. There is no need to identify a class or several comparators. It is also clear from NAFTA cases that the comparators should presumptively be in the same business or economic sector as the Claimant. In addition, if the comparators compete with the Claimant or its investments, this can be another indication of like circumstances.

Now, let me turn to the U.S. approach to the legal standards set out in Articles 1102 and 1103. The U.S. approach mixes things up in three important respects.

First, it mixes up treatment and like circumstances. It mixes up treatment by a State with voluntary actions by private enterprises. It mixes up discretion under national law with discretion to breach the Treaty. I will address each of these

points in turn.

First, treatment and like circumstances. The disputing Parties agree that facilities in the United States cannot be put on Import Alert because, by definition, these facilities do not offer products for import into the United States. They are already in the United States. Because domestic facilities cannot be put on Import Alert, the U.S. argues, investments supplied by such facilities and Marketing Authorizations reliant on such facilities cannot be in like circumstances with Apotex-U.S. and Apotex's Marketing Authorizations.

The U.S., based on this argument, attempts to eliminate from consideration all comparators supplied by pharmaceutical manufacturer on U.S. soil.

The U.S. relies on the Measure according treatment in its argument as the only pertinent circumstance. Nothing in the plain language of Articles 1102 or 1103, however, supports the U.S. argument.

I will first demonstrate the error in the U.S. argument and then demonstrate what circumstances

are appropriate to consider.

So let's begin with the text of Articles 1102 and 1103. As already noted, the text has two principle elements: Treatment and like circumstances.

"Accord" is the active verb in this sentence. "Treatment" is the object of that verb. "Treatment" means conduct, behavior or action towards someone. The terms "like circumstances" in Articles 1102 and 1103 directly qualify the verb "accord.

"Circumstances," as recognized by the ADM versus Mexico Tribunal, circumstances are conditions or facts that accompany an action. The relevant action in Article 1102 and 1103 is the according of treatment by a Party. The circumstances are not the action but, rather, the facts that accompany the action. To put it slightly differently, the circumstances are the set of facts that surround the according of treatment.

The text of Articles 1102 and 1103, thus, make clear that treatment and circumstances are two separate things. The U.S. argument mixes these two elements together.

The U.S. denied Apotex market access by adopting the Import Alert. This was the treatment accorded by the U.S. It is not, and under Articles 1102 and 1103 cannot be the circumstances surrounding the treatment. If one mixes up "treatment" and "like circumstances" as the U.S. does here, no claim could ever succeed under Articles 1102 or 1103.

We return to the mathematical formula that I referred to before. To prevail, an investor must show a difference in treatment; that it received less favorable treatment than investors and investments in like circumstances.

But under the U.S. theory, if the treatment received is not the same, the investor and the comparators cannot be in like circumstances. So what you have on the screen now is what a Claimant would need to show under the U.S. version of Article 1102 and 1103.

Where the treatment is the only relevant circumstance, any Claimant who demonstrates that the treatment is less favorable will necessarily have also

shown that the circumstances are not like. There would be no occasion in which a Party could be found to have breached Article 1102 or 1103.

The U.S. argument would render these two Articles ineffective and, as is well established, effectiveness is one of the primary principles of Treaty interpretation.

The three high fructose corn syrup cases nicely illustrate this point. The principal Measure In those three cases was a tax imposed on corn syrup but not on sugar. Under the U.S. theory, the producers of corn syrup could not be in like circumstances with sugar producers because the corn syrup producers had to pay the tax while the sugar producers did not have to pay the tax. Under the U.S. theory, this difference in treatment--whether or not the investor must pay the tax--would mean that the circumstances are not like.

Now, this is, of course, not how those three NAFTA Tribunals approached the issue. The corn syrup Tribunals--three different Tribunals, nine different arbitrators--all found that corn syrup producers and

sugar producers were in like circumstances. The Tribunals then concluded that Mexico was in breach of Article 1102 because it treated U.S. corn syrup producers less favorably than the Mexican sugar producers because of the tax.

Under the U.S. theory, the corn syrup Tribunals could not have found a breach of National Treatment because, according to the U.S., different treatment automatically means different circumstances. This argument is logically fallacious.

It is clear, therefore, that the Measure according the investment treatment cannot be part of the circumstances. The disputing Parties agree, however, that the legal regime in which the Measure is adopted is part of the circumstances relevant to assessing likeness.

Notably, the Parties are agreed that all circumstances must be taken into account in order to identify appropriate comparators. In particular, it is relevant to consider whether Apotex and the comparators are subject to the same legal regime. The question thus becomes: What aspects of the legal

regime are relevant to the circumstances?

Now, in the U.S. opinion, the legal regime is the Import Alert and only the Import Alert. Now, this assertion is legally inadmissible because, as we have just shown, the treatment cannot be the circumstance under NAFTA Articles 1102 and 1103.

The U.S. assertion is also difficult to reconcile with the position it has taken under the heading of "relating to." There, the U.S. contends that the only relevant Measure was FDA's determination that a given facility failed to comply with cGMP. The U.S., under the heading of "relating to," asserts that the Import Alert did not cause Apotex-U.S. to be cut off from its supplies; instead, according to the U.S., the pertinent Measure was FDA's cGMP findings.

By contrast, under the heading of "like circumstances," the Import Alert that supposedly had no causal relationship to Apotex-U.S.' ability to market its products, the Import Alert becomes the only relevant circumstance. The U.S. is arguing out of both sides of its mouth here.

Moreover, contrary to the U.S. position, it

is well established that the relevant legal regime cannot be reduced to just one type of enforcement action. To the contrary, as the S.D. Myers Tribunal found, the overall context should be taken into account as part of a like-circumstances analysis.

In Apotex's submission, the relevant legal regime here consists of the cGMP regulations for finished pharmaceutical products. These regulations, as is undisputed, equally apply to facilities inside and outside the United States.

In other words, Apotex and competing U.S. and third-country investors must comply with the same regulatory regime as concerns their investments in the pharmaceutical sector in the U.S. Under U.S. law, no investment can rely for its supply on products made by a facility that does not meet cGMP. In this case, an FDA finding of noncompliance with cGMPs makes investors and investments in like circumstances as concerns the legal regime.

Now, Apotex agrees with the U.S. that FDA has an additional means of banning products from the U.S. market when the facility is located abroad. The

record shows that products from a foreign facility can be subject to an Import Alert, injunction, or seizure. A domestic facility can be subject only to an injunction or seizure, but not an Import Alert.

But all of these enforcement Measures accord the same treatment: They ban from the U.S. market finished drugs that are found not to be manufactured in accordance with cGMP standards.

Apotex further agrees that, under U.S. law, the organ of the United States that adopts an injunction or seizure is not the same as the organ that adopts an Import Alert. In one instance, it is a court; and in another instance, it is FDA.

The Court and FDA have varying procedures that they follow in adopting Measures banning finished drug products from the market on cGMP grounds. These differences in the manner in which this treatment is accorded, however, do not change the analysis under Articles 1102 and 1103.

The NAFTA does not require that the treatment accorded by a Party be exactly the same. The language of Articles 1102 and 1103 expressly tolerates

differences in treatment as long as the treatment accorded the covered investment is no less favorable.

Here, I'd like to refer the Tribunal to the U.S. Statement of Administrative Action addressing Articles 1202 and 1203 of the NAFTA.

Now, these two Articles deal with National Treatment and MFN Treatment in the context of the cross-border trade and services. The provisions are identical in their structure to Articles 1102 and 1103 in the investment chapter.

The U.S. Statement of Administrative Action shows that the NAFTA Parties agree that there can be some legitimate differences in treatment between nationals and foreigners. However, from a qualitative perspective, the treatment cannot be less favorable to foreigners. What this means is that under Articles 1102 and 1103, Apotex did not have to receive the exact same treatment as the comparators supplied by facilities in the U.S. These two provisions of the NAFTA tolerate differences, but the NAFTA required that the treatment accorded Apotex be no less favorable than the treatment accorded these

comparators.

Now, in our presentations that will begin tomorrow, we will show at length that Apotex was not treated as well as the comparators.

Moreover, the U.S. argument--the U.S. provides no serious argument that there were legitimate regulatory distinctions--to use the language of the U.S. Statement of Administrative Action--that there were legitimate regulatory distinctions between foreign facilities and domestic facilities pertinent for these purposes.

The U.S. argues that foreign facilities do not pay taxes in the U.S., and that some advance notice is required for inspections of foreign facilities.

It also argues that it is easy for FDA to adopt an Import Alert because it can do so without any evidence and without having to persuade an independent decision maker that such action is warranted. While, for domestic facilities, FDA has to persuade a judge before such a potentially devastating Measure can be put into place.

None of these assertions withstand scrutiny. It may, indeed, be easier for the U.S. to accord less favorable treatment to Canadian investments in the U.S. that are supplied by Canadian facilities. Nothing in U.S. law, however, requires the U.S. to do so. The U.S. could decide to exercise its authority to adopt Import Alerts only where there is evidence supporting such an action. The fact that it is easy under U.S. law for the U.S. to accord less favorable treatment to Canadian investments supplied by Canadian facilities in no way justifies the differential treatment of comparable U.S. investments.

To conclude on this point, the comparators with facilities in the United States were in like circumstances to Apotex for a host of reasons that we will review tomorrow. The mere fact that these comparators cannot be subject to an Import Alert does not make them in unlike circumstances. The U.S. could have used other enforcement tools, such as injunctions or seizures, to ban from the U.S. market drugs made by Baxter, el Perico, Hospira, Sandoz Inc., and Teva Parenteral.

This goes to treatment. Under the plain terms of Articles 1102 and 1103, treatment cannot be the sole pertinent circumstance. The U.S. reliance on differences in treatment to argue like circumstances cannot be admitted.

I turn now to the second mixup made by the U.S. in its submissions. It mixes up treatment accorded by the host State with voluntary actions adopted by private persons like Teva or Sandoz, in our case. It alleges that alleged shutdowns--it argues that alleged shutdowns or slowdowns voluntarily adopted by Teva Parenteral and Sandoz reflect treatment accorded by FDA. This argument does not withstand scrutiny.

Under Articles 1102 and 1103, only treatment accorded by the host State is eligible for comparison.

The text in Article 1102, for example--1102(1)--is "Each Party shall accord to investors of another Party treatment no less favorable than that it accords in like circumstances to its own investor." Only treatment by a Party qualifies for the National Treatment or MFN analysis.

Now, this makes eminent sense. Articles 1102 and 1103 are provisions in a Treaty and engage the responsibility of States. For State responsibility to be engaged, acts attributable to the State must ordinarily be the basis for that responsibility. Voluntary acts undertaken by private actors of their own will do not qualify.

In its Rejoinder, the U.S. backs away from its position that voluntary acts are evidence of treatment by the United States. It now asserts that these acts illustrate the circumstances in which treatment by FDA was accorded. What was a defense on treatment in the Counter-Memorial becomes a defense on like circumstances in the Rejoinder.

Even construed as going to like circumstances, however, the defense is unsupported on the facts, as we will show tomorrow at some length.

But my point for now is that as a matter of law, the U.S. position that private Parties' acts qualify as treatment by a Party is untenable.

I come now to my final point before turning to the criteria for selecting the relevant

comparators. The U.S. mixes up "regulatory discretion" for purposes of judicial review under national law with "discretion to breach the NAFTA."

Now, as a preliminary matter, I note that in the written submissions, this argument was developed mainly in the Vodra Expert Report submitted with the U.S. Rejoinder. Mr. Vodra, in his Report, points out that courts lack authority under U.S. law to review FDA decisions not to enforce the law because these decisions reflect a discretionary weighing of various factors.

He argues that reading the text of NAFTA Articles 1102 and 1103 to mean what they say would eliminate all enforcement discretion owned by--enjoyed by FDA and drive all FDA enforcement to the lowest common denominator. He argues against this.

Now, this morning Ms. McLeod added a new variation of this argument. She began by characterizing Apotex's argument as follows--and I quote from the rough transcript from this morning at pages 37 to 38--"If FDA finds cGMP violations of regulatory significance with respect to a facility, it

must take the same enforcement action it has taken against another company with cGMP violations, regardless of the specific nature of the violations and any factors weighing for or against such action with respect to the particular facility."

So that's Ms. McLeod's characterization of Apotex's argument. That is not Apotex's position. Apotex's position is not that FDA must adopt the same enforcement action regardless of the circumstances. To the contrary, the NAFTA clearly gives FDA full authority to take circumstances into consideration in adopting Measures.

The only constraint on that authority is that FDA may not adopt Measures that are less favorable to covered investments in like circumstances.

Now, that position may sound familiar. If it does, it is because it is what Article 1102 and 1103 says. The treatment must not be no less favorable than that accorded in like circumstances.

Article 1102, as written, fully permits the circumstances to be taken into account. Apotex welcomes a discussion of the circumstances surrounding

FDA's action, and that, in fact, is what the bulk of our presentation on National Treatment and MFN will consist of.

Now, this morning Ms. McLeod also contended that--and I'm quoting now from pages 39 to 40 of the rough transcript--she contended that "The NAFTA Parties did not intend for investment Tribunals to sit retrospectively in judgment of the discretionary exercise of a sovereign power, particularly with respect to the protection of health and well-being of that sovereign's citizens."

She further argued that this Tribunal lacked the expertise to deal with technical issues such as these.

Now, with great respect to Ms. McLeod, that is not what the NAFTA provides.

The National Treatment and MFN Treatment provisions of the Treaty require an assessment of whether treatment accorded was in like circumstances Articles 1116 and 1117 of the NAFTA assign making this assessment to Arbitral Tribunals such as this one.

The Members of this Tribunal are amply

17:04:24 capable of assessing the arguments of the disputing Parties on the relevant circumstances, just as they have assessed a wide range of other equally technical issues in a wide variety of disciplines in other cases.

Each of the three NAFTA Parties has Government functions that involved the exercise of discretion. Each of the NAFTA Parties, nonetheless, agreed to respect the obligations that they undertook in the Treaty.

Article 1108 and the Annexes to the NAFTA allowed each Party to except from its obligations under Articles 1102 and 1103 those Measures that, for whatever reason, were deemed too sensitive to be subject to National Treatment and MFN obligations under those provisions. The U.S. included a number of Measures in those Annexes. Measures adopted under the Food, Drug, and Cosmetic Act, however, were not included.

Nothing in the NAFTA supports the suggestion that there should be an exception to Articles 1102 and 1103 for discretionary decisions. To the contrary,

17:05:50 Article 2101 of the NAFTA, which is the general exception provision--Article 2101 of the NAFTA sets out general exceptions to certain parts and chapters of the Treaty for Measures relating to health and safety.

Neither Chapter 11 on investment nor Part 5 of the NAFTA in which that chapter appears is mentioned. This general exception does not apply to Articles 1102 and 1103. There can be no doubt that Articles 1102, 1103 and, for that matter, 1105 fully apply to the FDA Measures here.

FDA may, indeed, have a certain degree of discretion under U.S. law in according treatment to regulated persons. It does not have discretion to breach the Articles of the NAFTA at issue in this case.

Mr. President, Members of the Tribunal, that concludes my discussion of the legal standard on National Treatment and Most-Favored-Nation Treatment.

I would now propose to turn the floor over to Ms. Dufêtre to address the bases for comparators, unless there is any question that the Tribunal has.

17:07:16 PRESIDENT VEEDER: No questions at this stage.

MR. LEGUM: Thank you.

MS. DUFÊTRE: Mr. President, Members of the Tribunal, now that Mr. Legum has explained the legal standards under Article 1102 and Article 1103, I will I will go through the criteria that were used to select Apotex's comparators.

Apotex submitted two Expert Reports prepared by Mr. Bradshaw and Mr. Johnson. These independent Experts helped identify comparators in like circumstances with Apotex, which all received less favorable treatment than Apotex.

And I will pause for a second.

PRESIDENT VEEDER: Let us catch up.

MS. DUFÊTRE: Sure.

So, Mr. Bradshaw and Mr. Johnson helped identify comparators in like circumstances with Apotex which all received less--more favorable treatment than Apotex.

The Members of the Tribunal will recall that Mr. Bradshaw served as FDA's chief counsel. In that

17:08:55 capacity, he reviewed hundreds of warning letters, and dozens of proposed enforcement actions. Mr. Johnson, for his part, was an FDA district officer, and he also headed the compliance office of an FDA center dealing with medical devices.

One of the principal questions posed to Mr. Bradshaw and Mr. Johnson was the following--and it is now on the screen. I quote: "Did the Import Alert adopted on August 28, 2009, with respect to all products produced at Apotex's Etobicoke and Signet facilities accord Apotex and its U.S. businesses treatment that was less favorable than that accorded in like circumstances to U.S. and foreign companies that owned comparable businesses?"

In other words, the question required Mr. Bradshaw and Mr. Johnson to identify comparators in like circumstances with Apotex and compare the treatment that the U.S. afforded Apotex, on the one hand, with the treatment that the U.S. afforded to its comparator on the other hand.

So in order to identify those comparators in like circumstances, Mr. Bradshaw and Mr. Johnson

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17:10:16 used--considered several criteria. First, each of the comparators is a pharmaceutical company, and as such, each comparator is an investor similar to Apotex.

Second, each comparator has investments in the United States similar to Apotex's investments. Each comparator owns or controls, directly or indirectly, a subsidiary in the United States that distributes and markets its products. Each comparator relies on sophisticated integrated manufacturing to supply the U.S. market. And in addition to that, each comparator owns or controls, directly or indirectly, Marketing Authorizations for each drug.

The third criterion is that each comparator operates in the same economic sector as Apotex.

Four, each comparator competes with Apotex on the U.S. pharmaceutical market.

The fifth criterion is that each comparator was a leading seller of generic drugs during the relevant period, 2008-2011.

The sixth criterion is that each comparator received one or several Warning Letters. And on that point, it is not in dispute that FDA issues Warning

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17:11:47 Letters only for cGMP violations of regulatory significance. So this is the criterion that was used, one of the main criterions, to select the comparators.

Now, this morning, Ms. McLeod insisted on FDA's technical expertise and the fact that this Tribunal is not equipped to second-guess FDA's determinations, but this is not what is asked from this Tribunal. The Tribunal does not need to assess the particulars of each cGMP deviations; instead, the facts that the comparators were issued Warning Letters for cGMP deviations, that fact indicates that they had like regulatory violations that were significant, and we think that this is the only relevant criterion, as opposed to going into the detail of each single cGMP violations.

ARBITRATOR CROOK: Sorry; I may be a little slow, but I thought I'm hearing the two of you saying something slightly different.

Is it the position, then, that like--the determination of a comparator in like circumstances is the receipt of a Warning Letter?

MR. LEGUM: For purposes of the legal regime,

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17:13:14 that's right. So that demonstrates that any comparator that received a Warning Letter for purposes of the applicable cGMP regime is in like circumstances.

Now, there may be other circumstances that can also be relevant, and we'll be discussing those at considerable length through the remainder of our presentation, but for purposes the legal regime, that's right.

ARBITRATOR ROWLEY: Well, the circumstances--one has the regime, but one can presumably look at the nature of concern that the FDA has, and if the concern is much more significant with respect to one of the comparators to another, then I think it's accepted that a different treatment can be accorded.

Am I right on that?

MR. LEGUM: Yes, we would agree with that.

ARBITRATOR ROWLEY: And as I understand the pleadings, your position is but if the U.S. takes that position, it ought to say why the concern is that much more significant.

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17:14:45 MR. LEGUM: Indeed.

MS. DUFÊTRE: So to try to summarize the criteria used by Mr. Bradshaw and Johnson--and I quote from the First Expert Report at Paragraph 1 of 7--they looked at the comparators--the quote is, "Comparable companies are large generic drug manufacturers of finished dosage forms as opposed to active pharmaceutical ingredients that have received an FDA Warning Letter during the 2008-2011 time period citing violations of the drug cGMPs."

Now, Mr. Bradshaw and Johnson also took into account the factors that were mentioned in FDA's three-page Memorandum of August 20, 2009, concerning the decision to recommend an Import Alert in Apotex's case. And notably, the presence of perceived repeats or corporate violations of cGMP. So repeat or corporate cGMP violations are also one important factor to be taken into account for the assessment of like circumstances.

Now, the U.S. has not challenged the criteria used by Apotex to identify the relative comparators, but, instead, the U.S. takes issue with one curious

17:16:26 fact that Mr. Bradshaw and Mr. Johnson pointed out in their First Expert Report. The fact is that Apotex's Expert could not identify during the relevant time period, 2008-2011, any U.S. investor or investment supplied by subsidiaries outside the United States that received a Warning Letter or Import Alert.

Apotex noted at this point in the Reply and Apotex also stated that the U.S. identified no U.S.-owned pharmaceutical company with subsidiaries outside the United States that were inspected by FDA and issued a Warning Letter for cGMP violations.

In its Rejoinder, the U.S. noted in a footnote that an Italian subsidiary of Pfizer--Pfizer being a U.S. company--that Italian subsidiary received a Warning Letter for its facility in Catania, Italy. That Warning Letter is dated March 27, 2013, and it is Exhibit R-220.

Now, if we look at what the U.S. stated about this Warning Letter, it's interesting in three respects: First, the U.S. confirms its understanding that the distribution companies in the United States are supplied by manufacturing companies which are

17:18:07 subsidiaries of the same pharmaceutical group. And you have the quote from the U.S. pleading on the screen.

The second observation is that the U.S. points out to a single Warning Letter, the one issued to Wyeth, its Pfizer subsidiary in Italy, and this Warning Letter, as I said, was issued on March 27, 2013, while Mr. Bradshaw and Mr. Johnson's Report was submitted on July 30, 2012.

The U.S. thus confirms that for the relevant period, 2008-2011, Mr. Bradshaw and Mr. Johnson's conclusion was correct. There was no U.S.-owned subsidiary outside the United States that received a Warning Letter.

And the third observation that I want that to make on this Warning Letter issued to Pfizer Italian subsidiary is that there is no dispute that this subsidiary has not been placed on Import Alert. In other words, Pfizer and its subsidiary received better treatment than Apotex.

PRESIDENT VEEDER: You referred to a footnote--you mentioned Pfizer. You mentioned a

17:19:37 footnote, Catania. Can you give us the reference?

MS. DUFÊTRE: The footnote is 538 from the U.S. Rejoinder.

MR. LEGUM: It appears on Slide 8.

MS. DUFÊTRE: May I proceed?

PRESIDENT VEEDER: Yes.

MS. DUFÊTRE: Okay. Thank you.

Based on the criteria that I have just recalled, Apotex and its Experts have identified five main comparators that were in like circumstances with Apotex and received more favorable treatment than Apotex. These comparators are Teva, Sandoz, Hospira, Baxter, el Perico. So Hospira, Baxter, and el Perico are all U.S. companies, and these comparators are used for the Claimant under 1102.

Now, with respect to Teva and Sandoz, these comparators serve for Apotex's claims both under Article 1102 and Article 1103.

Mr. Legum has explained that both provisions can be implemented for a single comparator, and that's the case here.

So for Sandoz, the company Sandoz Inc. is

17:21:08 incorporated in the United States, and it's of U.S. nationality. Sandoz Inc. manufactures and distributes products in the United States. And it owns scores of Marketing Authorizations. Therefore, Sandoz Inc. is a U.S. investor that can be used as a comparator for Apotex's National Treatment claim.

Sandoz Inc. is also indirectly owned and controlled by Novartis. Novartis is a Swiss company. So, in other words, Novartis is third-country investor which holds an investment in the United States in the form of Sandoz Inc. As such, Novartis and Sandoz Inc. can also be used as comparators for Apotex's Most-Favored-Nation Treatment claim.

The same applies to Teva. The company Teva Parenteral Inc. is incorporated in the United States and it is of U.S. nationality. It is a subsidiary of Teva Pharmaceuticals USA, which is also of U.S. nationality. These companies manufacture and distribute products in the United States. They also own scores of Marketing Authorizations and, therefore, these companies are U.S. investors that are used for Apotex's National Treatment claim.

17:22:35 At the same time, Teva Parenteral and Teva Pharmaceuticals USA are indirectly owned and controlled by Teva Pharmaceuticals Limited, which is an Israeli company. Teva Pharmaceuticals Limited is, thus, a third-country investor with investments in the United States. It follows that Teva Pharmaceuticals and its U.S. investments or its U.S. subsidiaries can also be used at comparators for Apotex's claim under Article 1103.

That concludes my presentation on the criteria for selected comparators.

PRESIDENT VEEDER: Thank you.

MR. LEGUM: Does the Tribunal have any questions at this point?

PRESIDENT VEEDER: Not at this stage.

MR. LEGUM: The Claimants would propose to break at this time and begin tomorrow morning first thing with the witness testimony.

PRESIDENT VEEDER: So your proposal is we break now and start again at 9:00 with your first witness--who will be the Expert?

MR. LEGUM: Mr. Bradshaw.

17:24:11 PRESIDENT VEEDER: Is it agreeable to the Respondent that we break now and resume at 9:00 tomorrow?

MS. GROSH: Yes, it is, Mr. President.

PRESIDENT VEEDER: We'll do that.

We just want to address before we leave whether we need one hour and a half for lunch, for the lunch break. Certainly I think for lunch it is probably not necessary, but you may have other things to do.

Have you thought about that? Could we save time by cutting the lunch hour back to one hour?

MR. LEGUM: That's fine for us, Mr. President.

MS. GROSH: That's fine for us as well, Mr. President.

PRESIDENT VEEDER: Let's do that. So we'll break just for one hour at lunchtime tomorrow. Until 9:00 tomorrow. Thank you very much.

MR. LEGUM: Thank you.

(Whereupon, at 5:25 p.m., the hearing was adjourned until 9:00 a.m. the following day.)

CERTIFICATE OF REPORTER

I, Dawn K. Larson, RDR, Court Reporter, do hereby certify that the foregoing proceedings were stenographically recorded by me and thereafter reduced to typewritten form by computer-assisted transcription under my direction and supervision; and that the foregoing transcript is a true and accurate record of the proceedings.

I further certify that I am neither counsel for, related to, nor employed by any of the parties to this action in this proceeding, nor financially or otherwise interested in the outcome of this litigation.

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DAWN K. LARSON